
From: Soukas, Peter (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B1F6020157AC47948C6E34166B78E433-SOUKASP]
Sent: 1/31/2019 6:50:52 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Request from Senator Sanders' office

Dear Mark,

Ok, thank you.

After I respond to your question today, Mike Mowatt will likely approve it tomorrow, so either tomorrow or Monday. Thank you.

Peter Soukas
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Phone: 301-594-8730
Email: ps193c@nih.gov

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Thursday, January 31, 2019 1:45 PM
To: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>
Subject: RE: Request from Senator Sanders' office

I am but we will not send until the response goes out to KEI. Do you have an estimated date?

From: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>
Sent: Thursday, January 31, 2019 1:41 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: RE: Request from Senator Sanders' office

Dear Mark,

I haven't been kept in the loop at all by OLPA nor have I been receiving any requests for documents.

We were under the assumption that you were providing the documentation to OLPA.

If you have access to any of this information and can provide it to us, we would appreciate it.

Thank you.

Peter Soukas
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Phone: 301-594-8730
Email: ps193c@nih.gov

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Thursday, January 31, 2019 1:21 PM
To: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>
Subject: RE: Request from Senator Sanders' office

Please send me a copy of the final after it goes out. Thx

REL0000023901

From: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>
Sent: Thursday, January 31, 2019 10:41 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Cc: Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>
Subject: FW: Request from Senator Sanders' office

Dear Mark, Dale and Mike,

FYI, thank you.

Peter Soukas
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Phone: 301-594-8730
Email: ps193c@nih.gov

From: [b6] (Budget) [b6] <@budget.senate.gov>
Sent: Thursday, January 31, 2019 10:39 AM
To: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura,

Good morning. When we spoke a week ago my understanding was that you would be sending over some background documents that you had on hand immediately following the call and would also get back to me "soon" with the documents we requested. When can we expect to receive that?

Thanks,

[b6]

From: [b6] (Budget)
Sent: Thursday, January 24, 2019 12:43 PM
To: 'Berkson, Laura (NIH/OD) [E]' <laura.berkson@nih.gov>
Cc: 'Soukas, Peter (NIH/NIAID) [E]' <peter.soukas@nih.gov>; 'Pollock, Rachel (NIH/OD) [E]' <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, thanks for calling yesterday. Could you send over those background/process documents you mentioned? We'll stand by for the substantive response. Happy to talk again about next steps once we see what you're able to provide.

Thanks,

[b6]

From: [b6] (Budget)
Sent: Wednesday, January 23, 2019 3:28 PM
To: 'Berkson, Laura (NIH/OD) [E]' <laura.berkson@nih.gov>
Cc: 'Soukas, Peter (NIH/NIAID) [E]' <peter.soukas@nih.gov>; 'Pollock, Rachel (NIH/OD) [E]' <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, I just left you a voicemail. Could you please give me a call as soon as possible? My direct is [b6]

Thanks,

[b6]

From: [b6] (Budget)
Sent: Wednesday, January 16, 2019 5:13 PM
To: 'Berkson, Laura (NIH/OD) [E]' <laura.berkson@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, any updates? I understand if this information may take a little time to assemble – in the meantime it would be terrific if it's possible to get the comment period extended. Thanks, [b6]

From: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Sent: Thursday, January 10, 2019 4:23 PM
To: [b6] (Budget) [b6]@budget.senate.gov
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi [b6]

We've reached out to our subject matter experts on this and will be back in touch soon.

Best,
Laura

Laura Berkson, J.D.
Office of Legislative Policy & Analysis
National Institutes of Health
(301) 496-3471 | laura.berkson@nih.gov

From: [b6] (Budget) [b6]@budget.senate.gov
Sent: Thursday, January 10, 2019 2:58 PM
To: Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Subject: RE: Request from Senator Sanders' office

Thanks Adrienne. Laura, I look forward to hearing from you soon. Thanks, [b6]

From: Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Sent: Wednesday, January 9, 2019 7:04 PM
To: [b6] (Budget) [b6]@budget.senate.gov
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Subject: Re: Request from Senator Sanders' office

Hi [b6]

Thanks for your note. I'm CC'ing Laura Berkson who will coordinate with NIAID to get you the information you need.

Hope you're enjoying the new Congress!
Adrienne

On Jan 9, 2019, at 5:04 PM, [b6] (Budget) [b6]@budget.senate.gov wrote:

Dear Mr. Soukas and Adrienne,

I hope you are both doing well. Would it be possible to extend the comment period for 83 FR 65696 [HHS Reference No. E-018-2018-0] regarding the provisional patent application entitled "Chimeric Vaccines?" My understanding from reading the FR notice is that the comment period began on December 21 and ran through just January 7. We'd appreciate additional time to review information regarding this important potential license that may have domestic and global public health implications.

To that end, could you send me a copy of the patent application and a list of the countries where NIH will file patents? I am attaching the letter from Knowledge Ecology International and Doctors Without Borders that was sent to your office; I respectfully request that in addition to providing this information to me, you also provide KEI and MSF with the information they are requesting in a timely way before making any decisions about the potential exclusive license.

Thank you, b6

b6

Senior Advisor on Poverty and Health
Senate Budget Committee
Ranking Member Bernie Sanders

b6 ps@budget.senate.gov

<Medigen Vaccines Biologics Corp. (Medigen), having a place of business i....pdf>

From: Marston, Hilary (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB30660917B942FFBA9AE95D631116F3-MARSTONHD]
Sent: 11/14/2017 5:29:36 PM
To: Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Eisinger, Robert (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bad2a8c45514ee48985880de66674ad-eisinger]
Subject: RE: KEI, MSF Comments Relating to Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection

My notes were unhelpful on this point, but Bob Eisinger's were better. Per Bob:

ASF addressed this on 9/5/17 with Larry, Mascola, Moffitt and the HHS Policy Team -Chris, Bob Kadlec, and Rick Bright.

From: Mowatt, Michael (NIH/NIAID) [E]
Sent: Tuesday, November 14, 2017 12:06 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Subject: Re: KEI, MSF Comments Relating to Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection

I believe it was one of the early calls with the department, I think when Larry and others from Bld 1 and our comma/leg folks attended.

Hilary can confirm.

On Nov 14, 2017, at 10:50 AM, Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov> wrote:

I am trying to remember when Dr. Fauci made the statement that NIAID ensured that there was no COI with respect to Kelly's consultations with NIAID. Maybe it was when talking with HHS. Who from NIAID would have been at those conference calls?

From: Mowatt, Michael (NIH/NIAID) [E]
Sent: Monday, November 13, 2017 4:19 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>
Subject: FW: KEI, MSF Comments Relating to Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection

Mark,

Amy just passed this along to me.

No responses to FRN other than these and KEI's previous two emails.

Mike

From: Petrik, Amy (NIH/NIAID) [E]
Sent: Monday, November 13, 2017 4:06 PM
To: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Salata, Carol (NIH/NIAID) [E] <csalata@niaid.nih.gov>; Feliccia, Vincent (NIH/NIAID) [E] <vfeliccia@niaid.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>
Cc: Contreras, Vince (NIH/NIAID) [E] <vince.contreras@nih.gov>
Subject: FW: KEI, MSF Comments Relating to Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection

Hi everyone,

Just received, FYI.

Thanks,
Amy

From: Andrew S. Goldman [<mailto:andrew.goldman@keionline.org>]
Sent: Monday, November 13, 2017 3:59 PM
To: Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>
Cc: Jamie Love <james.love@keionline.org>; Kim Treanor <kim.treanor@keionline.org>; Jennifer Reid <Jennifer.Reid@newyork.msf.org>
Subject: KEI, MSF Comments Relating to Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection

Dear Dr. Petrik:

On behalf of Knowledge Ecology International (KEI) and Médecins Sans Frontières (MSF), please see the two attached documents:

- (1) Comments submitted on behalf of both KEI and MSF on the proposed exclusive license of a Zika vaccine referred to in FR Vol. 82, No. 196 on October 12, 2017; and
- (2) Additional comments of KEI on potential conflicts of interest that create a compelling need for increased transparency with regard to the proposed license, and on additional proposals to limit the scope of exclusive rights.

If you have any questions with regard to these two documents, please let me know.

Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org

From: Berkson, Laura (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ADB561AB47E54FDC94E2A54682514434-BERKSONLD]
Sent: 1/24/2019 6:19:33 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Request from Senator Sanders' office

Thanks, Mark. I spoke with [b6] and told her we would not extend the comment period and that we were working on the response to KEI. She wanted to know when we thought the response would be ready. Anything specific I can tell her?

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, January 24, 2019 12:48 PM
To: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Subject: FW: Request from Senator Sanders' office

From: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>
Sent: Thursday, January 24, 2019 12:46 PM
To: Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: FW: Request from Senator Sanders' office

Dear Maryann, Rick, Suzanne, Mike, Dale and Mark,

FYI, thank you.

Peter Soukas
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Phone: 301-594-8730
Email: ps193c@nih.gov

From: [b6] (Budget) [b6] <budget.senate.gov>
Sent: Thursday, January 24, 2019 12:43 PM
To: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, thanks for calling yesterday. Could you send over those background/process documents you mentioned? We'll stand by for the substantive response. Happy to talk again about next steps once we see what you're able to provide.

Thanks,

[b6]

From: [b6] (Budget)
Sent: Wednesday, January 23, 2019 3:28 PM
To: 'Berkson, Laura (NIH/OD) [E]' <laura.berkson@nih.gov>

REL0000024290

Cc: 'Soukas, Peter (NIH/NIAID) [E]' <peter.soukas@nih.gov>; 'Pollock, Rachel (NIH/OD) [E]' <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, I just left you a voicemail. Could you please give me a call as soon as possible? My direct is [b6]
Thanks, [b6]

From: [b6] (Budget)
Sent: Wednesday, January 16, 2019 5:13 PM
To: 'Berkson, Laura (NIH/OD) [E]' <laura.berkson@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, any updates? I understand if this information may take a little time to assemble – in the meantime it would be terrific if it's possible to get the comment period extended. Thanks, [b6]

From: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Sent: Thursday, January 10, 2019 4:23 PM
To: [b6] (Budget) [b6] <budget.senate.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi [b6]

We've reached out to our subject matter experts on this and will be back in touch soon.

Best,
Laura

Laura Berkson, J.D.
Office of Legislative Policy & Analysis
National Institutes of Health
(301) 496-3471 | laura.berkson@nih.gov

From: [b6] (Budget) [b6] <budget.senate.gov>
Sent: Thursday, January 10, 2019 2:58 PM
To: Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Subject: RE: Request from Senator Sanders' office

Thanks Adrienne. Laura, I look forward to hearing from you soon. Thanks, [b6]

From: Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Sent: Wednesday, January 9, 2019 7:04 PM
To: [b6] (Budget) [b6] <budget.senate.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Subject: Re: Request from Senator Sanders' office

Hi [b6]

Thanks for your note. I'm CC'ing Laura Berkson who will coordinate with NIAID to get you the information you need.

Hope you're enjoying the new Congress!
Adrienne

On Jan 9, 2019, at 5:04 PM, [b6] (Budget) [b6] budget.senate.gov> wrote:

Dear Mr. Soukas and Adrienne,

I hope you are both doing well. Would it be possible to extend the comment period for 83 FR 65696 [HHS Reference No. E-018-2018-0] regarding the provisional patent application entitled "Chimeric Vaccines?" My understanding from reading the FR notice is that the comment period began on December 21 and ran through just January 7. We'd appreciate additional time to review information regarding this important potential license that may have domestic and global public health implications.

To that end, could you send me a copy of the patent application and a list of the countries where NIH will file patents? I am attaching the letter from Knowledge Ecology International and Doctors Without Borders that was sent to your office; I respectfully request that in addition to providing this information to me, you also provide KEI and MSF with the information they are requesting in a timely way before making any decisions about the potential exclusive license.

Thank you, Sophie

[b6]

Senior Advisor on Poverty and Health
Senate Budget Committee
Ranking Member Bernie Sanders

[b6]

budget.senate.gov

<Medigen Vaccines Biologics Corp. (Medigen), having a place of business i....pdf>

From: Soukas, Peter (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B1F6020157AC47948C6E34166B78E433-SOUKASP]
Sent: 2/14/2019 8:34:08 PM
To: Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Puglielli, Maryann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f53ceacaf754875a948081bac5cc66a-pugliellim]; Williams, Richard (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5f89fe4d27a43abb936bb20efeca3b9-rwilliams]; Frisbie, Suzanne (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c402740ceaad4d4f97a8c28f16fbb349-frisbies]
Subject: FW: Request from Senator Sanders' office

Dear Dale, Mark, Mike, Maryann, Rick and Suzanne,

FYI, thank you.

After a quick read through the questions, much of the information is not releasable as it is licensee confidential. I am not sure the Senator's office knows how many agreements we do in the aggregate at NIH per year. With respect to the last point, I believe it may be good to emphasize once again that we advertised this previously, there is a publication, and we do provide unpublished applications under CDA.

Peter Soukas
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Phone: 301-594-8730
Email: ps193c@nih.gov

From: [b6] (Budget) [b6] <budget.senate.gov>
Sent: Thursday, February 14, 2019 3:27 PM
To: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, thank you for this reply. I have a couple initial questions after reading this through.

- Your reply says that NIH will take steps to ensure that the proposed terms and scope of exclusivity are not greater than reasonably necessary. What are those steps? In what ways might or will NIH limit the proposed terms and scope of exclusivity? If you haven't taken those steps in this case yet and so cannot specify, please provide examples of steps NIH may take or has taken that might be applicable in this situation.
- Related – has NIH issued an exclusive license (let's say in the last 20 years) for a duration less than the full term of the patent? If so, which licenses, and what factors led to the decision to choose a term less than the life of the patent in that exclusive license?
- Your response mentions that your experienced licensing professionals obtain the best terms possible when negotiating these agreements, which are designed to improve the chances of successful development of the licensed therapy or vaccine and its distribution to patients throughout the world. Could you provide me with examples of these "best terms possible," including any provisions in existing exclusive licenses that address the policy objective set out in the US PHS Technology Transfer Policy Manual: "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."

- One of the things we requested was a copy of the patent application. I understand that this patent application is still provisional and has not yet been published. Does NIH license patent applications before they are available to the public? If so, why? Why does NIH open (and close) a public comment period before that information is available to the public?

Thanks, [b6]

From: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>

Sent: Thursday, February 7, 2019 4:47 PM

To: [b6] (Budget) <[b6]@budget.senate.gov>

Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>;

Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>

Subject: RE: Request from Senator Sanders' office

Hi [b6]

We really appreciate your patience as we pulled together this information. I'm happy to report that the response to KEI's letter to NIH was sent this week. I am attaching a document that includes some background about NIH and exclusive licenses and some information about the specific potential license in question. I hope you find it helpful.

Best,
Laura

From: [b6] (Budget) <[b6]@budget.senate.gov>

Sent: Thursday, February 7, 2019 4:17 PM

To: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>

Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>;

Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>

Subject: RE: Request from Senator Sanders' office

Hi Laura, we are still waiting to receive these documents. It's been a month - when will we receive the information requested?

Thanks,
[b6]

From: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>

Sent: Thursday, January 31, 2019 2:14 PM

To: [b6] (Budget) <[b6]@budget.senate.gov>

Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>

Subject: RE: Request from Senator Sanders' office

Hi [b6]

My apologies for the confusion. We are still prepared preparing the background information and formal response. We expect to have both complete and ready to send to you early next week.

Laura

From: [b6] (Budget) <[b6]@budget.senate.gov>

Sent: Thursday, January 31, 2019 10:39 AM

To: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>

REL0000024620

Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura,

Good morning. When we spoke a week ago my understanding was that you would be sending over some background documents that you had on hand immediately following the call and would also get back to me "soon" with the documents we requested. When can we expect to receive that?

Thanks,

b6

From: b6 (Budget)
Sent: Thursday, January 24, 2019 12:43 PM
To: 'Berkson, Laura (NIH/OD) [E]' <laura.berkson@nih.gov>
Cc: 'Soukas, Peter (NIH/NIAID) [E]' <peter.soukas@nih.gov>; 'Pollock, Rachel (NIH/OD) [E]' <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, thanks for calling yesterday. Could you send over those background/process documents you mentioned? We'll stand by for the substantive response. Happy to talk again about next steps once we see what you're able to provide.

Thanks,

b6

From: b6 (Budget)
Sent: Wednesday, January 23, 2019 3:28 PM
To: 'Berkson, Laura (NIH/OD) [E]' <laura.berkson@nih.gov>
Cc: 'Soukas, Peter (NIH/NIAID) [E]' <peter.soukas@nih.gov>; 'Pollock, Rachel (NIH/OD) [E]' <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, I just left you a voicemail. Could you please give me a call as soon as possible? My direct is 202-224-0560.

Thanks, b6

From: b6 (Budget)
Sent: Wednesday, January 16, 2019 5:13 PM
To: 'Berkson, Laura (NIH/OD) [E]' <laura.berkson@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, any updates? I understand if this information may take a little time to assemble – in the meantime it would be terrific if it's possible to get the comment period extended. Thanks, b6

From: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Sent: Thursday, January 10, 2019 4:23 PM
To: b6 (Budget) b6 budget.senate.gov
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi b6

We've reached out to our subject matter experts on this and will be back in touch soon.

REL0000024620

Best,
Laura

Laura Berkson, J.D.

Office of Legislative Policy & Analysis
National Institutes of Health
(301) 496-3471 | laura.berkson@nih.gov

From: [b6] (Budget) [b6] budget.senate.gov
Sent: Thursday, January 10, 2019 2:58 PM
To: Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Subject: RE: Request from Senator Sanders' office

Thanks Adrienne. Laura, I look forward to hearing from you soon. Thanks [b6]

From: Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Sent: Wednesday, January 9, 2019 7:04 PM
To: [b6] (Budget) [b6] budget.senate.gov
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Subject: Re: Request from Senator Sanders' office

H [b6]

Thanks for your note. I'm CC'ing Laura Berkson who will coordinate with NIAID to get you the information you need.

Hope you're enjoying the new Congress!
Adrienne

On Jan 9, 2019, at 5:04 PM, [b6] (Budget) [b6] budget.senate.gov wrote:

Dear Mr. Soukas and Adrienne,

I hope you are both doing well. Would it be possible to extend the comment period for 83 FR 65696 [HHS Reference No. E-018-2018-0] regarding the provisional patent application entitled "Chimeric Vaccines?" My understanding from reading the FR notice is that the comment period began on December 21 and ran through just January 7. We'd appreciate additional time to review information regarding this important potential license that may have domestic and global public health implications.

To that end, could you send me a copy of the patent application and a list of the countries where NIH will file patents? I am attaching the letter from Knowledge Ecology International and Doctors Without Borders that was sent to your office; I respectfully request that in addition to providing this information to me, you also provide KEI and MSF with the information they are requesting in a timely way before making any decisions about the potential exclusive license.

Thank you, [b6]

[b6]

Senior Advisor on Poverty and Health
Senate Budget Committee
Ranking Member Bernie Sanders

REL0000024620

b6

@budget.senate.gov

<Medigen Vaccines Biologics Corp. (Medigen), having a place of business i....pdf>

From: Wojtowicz, Emma (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=45C6610ACA6E44A08D497630425E5ECD-WOJTOWICZEM]
Sent: 3/16/2018 3:45:08 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Sovaldi Patent – Failed to Disclose Federal Funding?

Here is the next, thanks:

HHS is urged to investigate a Gilead hepatitis C patent for failing to disclose federal funding

By [ED SILVERMAN](#) [@Pharmelot](#)
MARCH 15, 2018

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A

n advocacy group asked the Department of Health and Human Services to investigate whether a key hepatitis C patent held by Gilead Sciences ([GILD](#)) failed to disclose federal funding for grants that were used to develop the blockbuster Sovaldi treatment.

In making its request, the advocacy group cited a federal database purportedly showing a patent awarded to Pharmasset, which developed Sovaldi, had received funding from the National Institutes of Health for four grants. The grants were provided between 2003 and 2006, and the patent was issued in June 2011, a few months before Gilead bought Pharmasset for \$11 billion.

Such a failure could have far-reaching implications for the drug maker and hepatitis C patients, because federal law would permit the government to take title to the patent. In its March 14 [letter](#), the advocacy group suggested such a move might allow the government to reach a marketing agreement with the company that could, ultimately, lead to lower prices for public and private payers.

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“Gilead would have to get a license from the government to continue providing the product and the government could make money off a royalty and also solve some other problems, such as affordability and access,” said Jamie Love of Knowledge Ecology International, the advocacy group. “The government would have enormous leverage over the price of the drug.”

Whether the HHS will investigate whether funding for the patent was properly disclosed is uncertain. We asked the agency for comment and will update you accordingly. Meanwhile, a Gilead spokeswoman wrote us that “our policy is to fully disclose appropriate grants (and) contributions. We are reviewing KEI’s letter and cannot comment beyond that.”

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[Hospitals are confronting a new opioid crisis: an alarming shortage of pain meds](#)

Under a [federal law](#) known as the Bayh-Dole Act, as well as federal regulations, a grant recipient is [required](#) to disclose federal funding that contributed to an invention, and include language in patent applications and any patent describing the role the funding played. The advocacy group contended Pharmasset failed to take this step for the patent, which is linchpin of the Gilead hepatitis C franchise.

The move to push the HHS to investigate the patent is part of a broader effort to widen access to high-priced medicines, notably hepatitis C treatments, which have strained payer budgets over the last several years and created dilemmas for some patients. When Sovaldi first became available four years ago, the drug cost \$1,000 a pill, or \$84,000 for a regimen, before rebates or discounts.

The pill was quickly and widely prescribed because it was the first in a new generation of treatments that offered cure rates of 90 percent or more, and with few appreciable side effects. But with no initial competition, Gilead offered few rebates or discounts, and the sudden impact of a large number of patients prompted state Medicaid programs and prisons, for instance, to restrict access, despite [projected](#) long-term savings.

Since then, Gilead has used Sovaldi as the cornerstone of a lucrative hepatitis C product line, although more recently, competition has driven down pricing. Last year, AbbVie ([ABBV](#)) began selling a treatment called Mavyret that has a wholesale price of \$26,400. And as more patients are treated, Gilead hepatitis C product sales have fallen from \$19.2 billion in 2015 to \$9.1 billion last year.

Top of Form

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Nonetheless, the cost remains an issue. Some states continue to impose various restrictions that impede access to treatment, according to a recent [analysis](#) by the Center for Health Law and Policy Innovation of Harvard Law School. And inmates in Indiana, Pennsylvania, Missouri, Minnesota, and Tennessee have filed lawsuits accusing prison systems of denying them access.

Last week, prisoners in Massachusetts settled a class-action lawsuit that accused the state Department of Correction of violating their constitutional rights and permanently impairing their health for failing to make hepatitis C treatments available. The settlement calls for clear guidelines to evaluate and track inmates with hepatitis C, according to this [court document](#).

Other efforts are under way to widen access to hepatitis C treatments.

Last month, a group of congressional Democrats [urged](#) the HHS to tap a little-known 1910 law that would allow the government to sidestep patents on hepatitis C medicines. Under the [law](#), HHS could use a patented invention without permission, and a drug maker could demand “reasonable” compensation — such as royalties — but cannot stop the government from taking such a step.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Friday, March 16, 2018 11:41 AM
To: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: Fwd: Sovaldi Patent – Failed to Disclose Federal Funding?

Do you have access to the STAT article? Thx

Sent from my iPhone

Begin forwarded message:

From: "Koniges, Ursula (NIH/OD) [E]" <ursula.koniges@nih.gov>
Date: March 16, 2018 at 9:33:33 AM EDT
To: "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>, "Dodson, Sara (NIH/OD) [E]" <sara.dodson@nih.gov>
Subject: Sovaldi Patent – Failed to Disclose Federal Funding?

HHS Is Urged To Investigate A Gilead Hepatitis C Patent For Failing To Disclose Federal Funding. STAT Plus (3/15, Silverman, Subscription Publication, 45K) reports the advocacy group Knowledge Ecology International urged the Department of Health and Human Services to investigate whether “a key hepatitis C patent held by Gilead Sciences (GILD) failed to disclose federal funding for grants” from the National Institutes for Health that “were used to develop the blockbuster Sovaldi treatment.” The group contends that Gilead’s failure could permit the government to “take title to the patent.”

From: Wong, Jennifer (NIH/NIMH) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C4258C7CF58F4945A3DF079942C68852-WONGJE]
Sent: 3/15/2018 5:24:31 PM
To: Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Campbell, Eggerton (NIH/NHGRI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8315e00da5245d3b97ed244f5092ffb-campbellea2]
Subject: Final Determination memo
Attachments: A-381-2017-0_Final Determination_signed.pdf

FYI

Jennifer Wong, M.S.
Technology Development Coordinator
National Institute of Mental Health
Office of Technology Transfer
35A Convent Drive, Room GE400
Bethesda, MD 20892-3747
Phone: 301-480-4821
E-mail: wongje@mail.nih.gov

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REL0000024670



ELCG DATE: 13 September 2017

TO: Richard U. Rodriguez, M.B.A.
Associate Director, TTC, NCI

THROUGH: Laurie Whitney, Ph.D.
Unit Supervisor, TTC, NCI

Laurie W. Whitney -S

Digitally signed by Laurie W. Whitney
DN: c=US, o=U.S. Government,
ou=HHS, ou=NIH, ou=People,
0.9.2342.19200300.100.1.1=DD10750
55.1.cn=Laurie W. Whitney-S
Date: 2017.10.03 14:19:50 -0400

FROM: David Lambertson, Ph.D.
Senior Technology Transfer Manager, TTC, NCI

SUBJECT: Final Determination for an exclusive license application [b4] from Salubris
Biotherapeutics, Inc. for a license to NIH technology references [b5]

With the submission of [b4] Salubris Biotherapeutics, Inc. (Salubris) applied for a worldwide exclusive license for patents and/or patent applications in the [b5] technology families. A Preliminary Determination was presented to the Exclusive Licensing Consultation Group on 19 July 2017, and a decision was made to advertise the intent to grant Salubris an exclusive license in the following field of use:

“The development and commercialization of a bispecific, biparatopic antibody-drug conjugate (ADC) having:

- 1) the CDR sequences of both the hYP7 and HN3 anti-GPC3 monoclonal antibodies; and
- 2) a microtubule inhibitor payload including, but not limited to, auristatin and mertansine;

for the treatment of human liver cancer. The licensed field of use excludes any (a) non-specified immunoconjugates, including, but not limited to, chimeric antigen receptors (CARs) and variants thereof, immunotoxins, ADCs with payloads that are not microtubule inhibitors, and monospecific versions of the aforementioned immunoconjugates, and (b) unconjugated antibodies.”

The Notice of Intent to Grant (see attachment) was published in Volume 82, No. 150 (pages 36808-36809) of the *Federal Register* on 7 August 2017 setting forth the above advertised field of use. The fifteen (15) day notice period for the publication ended on 22 August 2017, and a total of eight (8) objections were received from the following individuals/groups/companies:

- 1) Knowledge Ecology International (KEI) provided comments and questions objecting to the grant of the license.
- 2) Samer Nuwayhid provided comments objecting to the grant of the license (see attached).
- 3) Bruce Korb provided comments objecting to the grant of the license (see attached).
- 4) Arnold Shugarman provided comments objecting to the grant of the license (see attached).
- 5) David Kolstedt provided comments objecting to the grant of the license (see attached).
- 6) Brinsley Davis provided comments objecting to the grant of the license (see attached).
- 7) Paul Stumpf provided comments objecting to the grant of the license (see attached).
- 8) [b4] application (see attached).



These objections will be addressed as follows:

- 1) The comments (items #1-7 above) will be considered the “First Class of Objections” and addressed collectively due to the similarity of the subject matter of the comments
- 2) The objecting application will be considered the “Second Class of Objections” and addressed as a separate item.
- 3) A conclusion will then be drawn on how to proceed with the b4 application will be offered at the end of the Final Determination, based on a consideration of both classes of objections.

FIRST CLASS OF OBJECTIONS- QUESTIONS, COMMENTS AND REQUESTS

As previously noted, NIH received seven (7) objections in the form of comments, without the submission of a competing license application. A summary of the commenters and their specific comments is listed below, in the order of their receipt.

- 1) KEI provided the following requests and comments:
 - a. KEI requested several details about the applicant and the terms and conditions of the license (which has not been negotiated in any detail), including:
 - i. the name of the parent company for the applicant;
 - ii. the duration of the proposed license;
 - iii. the proposed royalty rate of the license;
 - iv. the amount of money spent by federal agencies to develop the invention; and
 - v. the terms included in the license to ensure fair pricing, and the steps taken by NIH to ensure the license will be in compliance with 35 USC 209 (ensuring the scope is not greater than reasonably necessary).
 - b. KEI requested that the license contain
 - i. terms and conditions regarding the pricing of any products resulting from the license,
 - ii. requirements that the licensee disclose business confidential information about itself during the duration of the license, and
 - iii. a requirement that the licensee make materials and protocols available to generic companies for production in OECD countries or for WHO prequalification.
 - c. KEI comments that, despite the fact that 35 USC 209(f) has been used to reject their requests for transparency from the licensee, 35 USC 209(f) does not specifically preclude the NIH from requiring the licensee to publicly disclose reports on how they are investing in and marketing a product obtained under an exclusive license.
- 2) Samer Nuwayhid:
 - a. Objected to the grant of an exclusive license to a foreign-controlled company with no controls over the pricing of the drug;
 - b. Asked if U.S. companies were given the opportunity to compete for this exclusive patent license; and
 - c. Asked why the NIH was doing this in secrecy.
- 3) Bruce Korb asked:
 - a. If the government was getting the proper return on investment through the license;
 - b. What value the company was providing to the government in return for the license; and
 - c. If it is the best interests of United States citizens to have an exclusive license granted to a company that can charge whatever it wants for the medicine developed under the license.



-
- 4) Arnold Shugarman indicated that no company should receive exclusivity for a drug that was developed using taxpayer dollars, and suggested that the license should contain fair pricing restrictions.
 - 5) David Kolstedt indicated that taxpayers should benefit from inventions they paid to develop, and suggested that any license should contain fair pricing restrictions.
 - 6) Brinsley Davis objected to the grant of the license in the absence of fair pricing restrictions.
 - 7) Paul Stumpf objected to the grant of an exclusive license to a company that is “ultimately controlled by a wealthy Chinese.”

The comments and requests provided above do not provide sufficient reason to preclude moving forward with the negotiation of a license with Salubris for the following reasons:

- 1) KEI has not made a sufficient case to prevent the grant of the license to Salubris with their comments and requests for the following reasons:
 - a. It is first noted that none of the terms of the proposed license have been negotiated, so many of KEI's requests cannot be answered at this time. Even if the requested answers were, are or become available, the proper avenue for obtaining any information about the license and application should be via a request to the FOIA Office. Regardless, requests for information about the license and license applicant do not themselves provide a rationale for preventing the license.
 - b. There are no statutes or regulations that require an exclusive license from NIH to contain terms and conditions related to (i) fair pricing of resulting products, (ii) the disclosure of business confidential information about the licensee, or (iii) the release of licensee-developed materials and protocols for practicing the invention. Indeed, (attempts at) the inclusion of terms and conditions related to fair pricing has historically been unfavorable, resulting in fewer NIH inventions being licensed and subsequently developed into therapeutic products that benefit public health. It is likely that requiring a company to release information about itself or the protocols it has developed will have the same effect. Since there is no legal basis to require fair pricing terms or disclosure requirements in the license, requests that a license not be negotiated without such terms are insufficient to preclude the negotiation of an exclusive license.
 - c. It is noted that, while 35 USC 209(f) does not preclude the Federal Government from requiring a company to disclose business confidential information about its research, development and investment practices, it neither permits nor requires it, either. The fact remains that KEI has not provided a reference to an existing U.S. statute or regulation that requires NIH to include the terms and conditions that it is requesting in an exclusive license. While NIH *may* pursue all, some, or none of these requested terms and conditions during the negotiation of the license, the ultimate inclusion or exclusion of any such terms and conditions is a matter of negotiation, and not a matter of law.
- 2) Samer Nuwayhid's comments are insufficient to prevent negotiating the proposed license with Salubris because they do not raise a legal impediment to the grant. Specifically:
 - a. The issue on fair pricing terms and conditions is addressed above in the response to point #1, and applies equally here.
 - b. The technologies proposed for licensing have been advertised since 2011 and 2012, respectively, so every company (including U.S. companies) has been given the opportunity to pursue the proposed license. Although no other company had applied for a license in the proposed field of use prior to the publication of the Notice of Intent to Grant for the subject



application, a competing application was received in response to the Notice (see below for details on the competing application). The requirement for advertising the availability of a technology for licensing (37 CFR 404.4) and the intent to grant an exclusive license (37 CFR 404.7(a)(1)(i)) have been met.

- c. The NIH publicly disclosed its intent to grant this license in accordance with 37 CFR 404.7(a)(1)(i); as a result, the comment that this license is being negotiated in secrecy is factually incorrect.
- 3) Bruce Korb's questions are insufficient to preclude the pursuit of the proposed license with Salubris because they do not raise a legal impediment to the grant. The questions are not in-and-of-themselves a rationale for not granting the license. Notwithstanding the preceding, the NIH believes that any license that is successfully negotiated will procure a value that represents a good return on its investment, and that the resulting development of a new treatment for an unmet need (liver cancer) will be of great benefit to the public.
- 4) Arnold Shugarman's comments are insufficient to preclude the grant of the proposed license because they do not raise a legal impediment to the grant. As previously noted, there is no legal requirement for including terms and conditions regarding fair pricing in an NIH license. Furthermore, the statement that the technology being licensed was "developed with taxpayer dollars" is a gross mischaracterization of the invention; the invention is not remotely "developed" as it requires an enormous amount of additional work before a product can be brought to market.
- 5) David Kolstedt's comments are insufficient to preclude the grant of the proposed license because they do not raise a legal impediment to the grant. As previously noted, there is no legal requirement for including terms and conditions regarding fair pricing in an NIH license. Furthermore, the public will benefit from the development of a new therapeutic to a disease that currently has limited treatment options.
- 6) Brinsley Davis's comments are insufficient to preclude the grant of the proposed license because they do not raise a legal impediment to the grant. As previously noted, there is no legal requirement for including terms and conditions regarding fair pricing in an NIH license.
- 7) Paul Stumpf's comments are insufficient to preclude the grant of the proposed license because they do not raise a legal impediment to the grant. There are no legal grounds set forth in 37 CFR 404.5 for denying a license to a company simply because they are "ultimately controlled by" a foreign entity. While there is a preference for small businesses (37 CFR 404.7(a)(1)(C)(iv)), said small businesses must have submitted a plan that is "determined by the agency to be within the capability of the firm[s] and as having equal or greater likelihood as those from other applicants to bring the invention to practical application within a reasonable time." In this case, Salubris has provided an adequate plan for bringing the invention to practical application in a reasonable amount of time, which no other company has accomplished (see also the analysis of the competing application in the section below).

In conclusion, none of the comments provides a legal basis for preventing the negotiation of the proposed license with Salubris. The Preliminary Determination adequately established that the Federal regulations regarding the grant of an exclusive license to an NIH invention were met, and the comments have not established any grounds that the determination was inaccurate or that a Federal regulation or statute has not been met.

NCI believes it has adequately addressed all of the objections proposed by the commenters. Each commenter will be informed, via a letter sent by e-mail, of NCI's decision to move forward with an exclusive license to Salubris in the proposed Licensed Field of Use.



SECOND CLASS OF OBJECTIONS- COMPETING APPLICATIONS

On 22 August 2017, a group identifying itself as:

b4

b4



b4



b4

CONCLUSION AND NEXT STEP IN THE LICENSING PROCESS

NCI has given full consideration to the eight (8) objections as set forth above, and has determined that none of the objections were sufficient to preclude the grant of an exclusive license to Salubris under the **b4** application. NCI believes the requirements of 37 CFR 404 have been fulfilled as outlined in the Preliminary Determination for license application **b4** and that an exclusive license to Salubris with the field of use as advertised in the Notice of Intent to Grant would promote the development and implementation of these technologies.

With your approval of this determination, indicated by your signature below

b4

b4

SIGNATURE

Richard U.
Rodriguez -S

Digitally signed by Richard U.
Rodriguez -S
Date: 2017.10.03 14:32:12 -04'00'

Richard U. Rodriguez
Associate Director, TTC, NCI

Date

Attachments:

- Copy of *Federal Register* Notice (2 pages)
- Objection Filed by KEI (5 pages)
- Objection Filed by Samer Nuwayhid (1 page)
- Objection Filed by Bruce Korb (2 pages)
- Objection Filed by Arnold Shugarman (1 page)
- Objection Filed by David Kolstedt (1 page)
- Objection Filed by Brinsley Davis (1 page)
- Objection Filed by David Kolstedt (1 page)

b4

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=591AB6B2424B4B8997082718CBB29FAB-ROHRBAUM]
Sent: 8/28/2019 4:27:09 PM
To: Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]
CC: Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]
Subject: Re: 84 FR 33272, 84 FR 33270

b5

correct?

Dale?

Sent from my iPhone

On Aug 28, 2019, at 10:18 AM, Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov> wrote:

KEI sent the e-mail below last night. b5 I wanted to see if b5

b5

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
Phone (direct): (240) 276-6467
Fax: 240-276-5504

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From: James Love <james.love@keionline.org>
Sent: Tuesday, August 27, 2019 6:45 PM
To: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Cc: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: Re: 84 FR 33272, 84 FR 33270

More generally, are the three types of blood cancers specifically mentioned exhaustive in terms of the field of use for the license?

On Tue, Aug 27, 2019 at 4:08 PM kathryn ardizzone <kathryn.ardizzone@keionline.org> wrote:

REL0000024678

Dear Dr. Lambertson:

With regard to the licenses referenced in the federal register notices at 84 FR 33272 and 84 FR 33270, can you please clarify whether the cancers potentially targeted by those licenses are limited to the diseases listed on the notices (Non-Hodgkin lymphoma, acute lymphoblastic leukemia, and chronic lymphocytic leukemia), or could other diseases, such as Hodgkin Lymphoma, potentially be treated?

Thank you,

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

--

James Love. Knowledge Ecology International
U.S. Mobile +1.202.361.3040
U.S. office phone +1.202.332.2670
<http://www.keionline.org>
twitter.com/jamie_love

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=591AB6B2424B4B8997082718CBB29FAB-ROHRBAUM]
Sent: 8/27/2019 2:56:04 PM
To: Shmilovich, Michael (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dfe19bfd1d443ceb700b9f22d159a90-shmilovm]
CC: Knabb, Jim (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=535517d229e04963a2b928742cb80da0-knabbjr]
Subject: Response to KEI questions

Misha:

I cannot pull up your response to KEI questions last week. Could you please send them to Jim as he is getting similar questions from the new attorney.

Thanks
Mark
Sent from my iPhone

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 5/4/2017 8:31:32 PM
To: Plude, Denise (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=parksde]
Subject: Fwd: Response Creation - Edits required (WF 357204) DUE by 2pm April 4th
Attachments: Response 05042017 KEI request REV4 ahmr.docx; ATT00001.htm

Sent from my iPhone

Begin forwarded message:

From: "Hammersla, Ann (NIH/OD) [E]" <hammerslaa@mail.nih.gov>
Date: May 4, 2017 at 4:17:58 PM EDT
To: "Brandy, Aesha (NIH/OD) [C]" <aesha.brandy@nih.gov>, "Bulls, Michelle G. (NIH/OD) [E]" <michelle.bulls@nih.gov>
Cc: "Helfer, Jacqueline (NIH/OD) [C]" <jacqueline.helfer@nih.gov>, "Bundesen, Liza (NIH/OD) [E]" <lbundese@od.nih.gov>, "Kitt, Cheryl (NIH/OD) [E]" <kittc@od.nih.gov>, "Joshi, Pritty (NIH/OD) [E]" <pritty.joshi@nih.gov>, "Showe, Melanie (NIH/OD) [E]" <showem@od.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <Michael.Lauer@nih.gov>, "Black, Jodi (NIH/OD) [E]" <Jodi.Black@nih.gov>, "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Subject: RE: Response Creation - Edits required (WF 357204) DUE by 2pm April 4th

Dear Aesha:

Attached is mine and Mark's re-worked response to KEI's march-in request. This has been ok'd by OSP and was sent to Dale and Barbara earlier this afternoon. I have not received comments back from OGC.

Please let me know if you need anything further.

Ann

From: Brandy, Aesha (NIH/OD) [C]
Sent: Wednesday, May 03, 2017 2:18 PM
To: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Cc: Helfer, Jacqueline (NIH/OD) [C] <jacqueline.helfer@nih.gov>; Bundesen, Liza (NIH/OD) [E] <lbundese@od.nih.gov>; Kitt, Cheryl (NIH/OD) [E] <kittc@od.nih.gov>; Joshi, Pritty (NIH/OD) [E] <pritty.joshi@nih.gov>; Showe, Melanie (NIH/OD) [E] <showem@od.nih.gov>
Subject: Response Creation - Edits required (WF 357204) DUE by 2pm April 4th

Good Afternoon -

Attached are copies of the draft response documents that were submitted to the NIH Exec Sec review and approval. See the highlighted comments below from OGC and make the updates accordingly. Please return to me by 2pm Thursday April 4th to allow OER reviewers time to preview draft.

Do not hesitate to contact me should you have any questions or concerns.

Thanks,
Aesha

REL0000024686

Work Folder Information

Work Folder: WF 357204

Process: Necessary Action

Program Analyst: Hurlebaus, Lisa (NIH/OD) [E]

Due Date: May 04, 2017

WF Subject: OS assignment. KEI & UACT write about the prostate cancer drug, Xtandi (enzalutamide). Asks the Government to reconsider the decision not to use the 'march-in' rights, under the Bayh-Dole Act, for this excessively-priced drug. (AS-760889)

IC: od_oer

From: Goldman, Andrew

To: Price, TomMattis, Jim

Remarks: b5

b5

Additional instructions are included on the task form, click the link to open the [Task](#)

Andrew S. Goldman
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, D.C. 20009

Dear Mr. Goldman:

b5

b5

Sincerely yours,

Francis S. Collins, M.D., Ph.D.
Director

cc: The Honorable James Mattis
Secretary of Defense

The Honorable Tom Price
Secretary of Health and Human Services

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 5/8/2017 6:06:38 PM
To: Plude, Denise (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=parksde]
Subject: Re: ES - WF 357204 - Necessary Action (CC)

Yes

Sent from my iPhone

On May 8, 2017, at 2:00 PM, Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov> wrote:

Can Exec Sec proceed?

From: Hurlebaus, Lisa (NIH/OD) [E]
Sent: Monday, May 08, 2017 1:59 PM
To: Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov>
Subject: RE: ES - WF 357204 - Necessary Action (CC)

Hey Denise,
OGC has cleared the latest response without further comment. I won't send forward to Dr. Tabak yet, until I hear from you. Thanks, Lisa

From: Plude, Denise (NIH/OD) [E]
Sent: Monday, May 08, 2017 1:10 PM
To: Hurlebaus, Lisa (NIH/OD) [E] <marshall@od.nih.gov>
Subject: RE: ES - WF 357204 - Necessary Action (CC)

Hi Lisa, would you please hold off on this? I need to get some clarification from the staff that was assigned on this. Please let me know if OGC clears without comment but please do not send yet. Thank you.

From: Hurlebaus, Lisa (NIH/OD) [E]
Sent: Monday, May 08, 2017 11:57 AM
To: Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov>
Subject: RE: ES - WF 357204 - Necessary Action (CC)

I wasn't planning to send it back to OSP for clearance, unless OGC has more clearance comments. OGC is clearing now and, if they concur, the version wouldn't change from what you sent me on Friday. So, I would send to Dr. Tabak for clearance and Dr. Collins for signature.

Is there a reason OSP needs to see the draft again?

From: Plude, Denise (NIH/OD) [E]
Sent: Monday, May 08, 2017 10:46 AM
To: Hurlebaus, Lisa (NIH/OD) [E] <marshall@od.nih.gov>
Subject: RE: ES - WF 357204 - Necessary Action (CC)

Hi Lisa, will this come back for another clearance?

Work Folder Information

Work Folder: WF 357204

Process: Necessary Action

Program Analyst: Hurlebaus, Lisa (NIH/OD) [E]

Due Date: May 04, 2017

WF Subject: OS assignment. KEI & UACT write about the prostate cancer drug, Xtandi (enzalutamide). Asks the Government to reconsider the decision not to use the 'march-in' rights, under the Bayh-Dole Act, for this excessively-priced drug. (AS-760889)

IC: od_osp

From: Goldman, Andrew

To: Price, TomMattis Jim

Remarks:

b5

b5

Additional instructions are included on the task form, click the link to open the [Task](#)

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 5/4/2017 2:20:52 PM
To: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: Re: royalties

Thx

Sent from my iPhone

On May 4, 2017, at 10:08 AM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:

I think that we can also:

b5

b5

b5

From: Hammersla, Ann (NIH/OD) [E]
Sent: Thursday, May 04, 2017 9:57 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: royalties

Good Morning: I am just pulling up the OGC comments.

b5

b5

b5

If you would like to
draft I am on-line for most of the morning. Ann

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, May 04, 2017 9:47 AM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: Re: royalties

The revised KEI letter is due today. If I take a stab at it, are you able to look it over today?

Sent from my iPhone

On May 4, 2017, at 9:32 AM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:

Good Morning: Thanks Mark for adding the additional information. I am at the NIH Regional meeting and yesterday was a workshop on IP.

Ann

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, May 03, 2017 4:36 PM
To: Tabak, Lawrence (NIH/OD) [E] <Lawrence.Tabak@nih.gov>
Cc: Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: RE: royalties

I believe Ann is on official travel. Here is my revision.

From: Tabak, Lawrence (NIH/OD) [E]
Sent: Wednesday, May 03, 2017 2:33 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Cc: Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>
Subject: royalties
Importance: High

Mark, Ann-

Please see FC comments on your proposal. Could you please address questions/comments and return to me asap?

Thanks
Larry

REL0000024689

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 5/3/2017 4:57:19 PM
To: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: Fwd: WF 357204 - Necessary Action - due 5/4
Attachments: DR01 Goldman Dir Sig 5.1.17.docx; ATT00001.htm

Can we

b5

Sent from my iPhone

Begin forwarded message:

From: "Plude, Denise (NIH/OD) [E]" <pludedc@mail.nih.gov>
Date: May 3, 2017 at 11:55:42 AM EDT
To: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Cc: "Wertz, Jennifer (NIH/OD) [E]" <wertzj@od.nih.gov>
Subject: WF 357204 - Necessary Action - due 5/4

Work Folder Information

Work Folder: WF 357204

Process: Necessary Action

Program Analyst: Hurlebaus, Lisa (NIH/OD) [E]

Due Date: May 04, 2017

WF Subject: OS assignment. KEI & UACT write about the prostate cancer drug, Xtandi (enzalutamide). Asks the Government to reconsider the decision not to use the 'march-in' rights, under the Bayh-Dole Act, for this excessively-priced drug. (AS-760889)

IC: od_osp

From: Goldman, Andrew

To: Price, TomMatis, Jim

Remarks:

b5

b5

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 5/4/2017 6:39:27 PM
To: Plude, Denise (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=parksde]
Subject: Re: WF 357204 - Necessary Action - due 5/4

We asked OGC to review it. I will see if they can turn it around quickly

Sent from my iPhone

On May 4, 2017, at 2:18 PM, Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov> wrote:

Is this almost ready?

From: Plude, Denise (NIH/OD) [E]
Sent: Thursday, May 04, 2017 9:37 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: WF 357204 - Necessary Action - due 5/4
Importance: High

Due today.

From: Plude, Denise (NIH/OD) [E]
Sent: Wednesday, May 03, 2017 11:56 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Wertz, Jennifer (NIH/OD) [E] <wertzj@od.nih.gov>
Subject: WF 357204 - Necessary Action - due 5/4
Importance: High

Work Folder Information

Work Folder: WF 357204

Process: Necessary Action

Program Analyst: Hurlbaums, Lisa (NIH/OD) [E]

Due Date: May 04, 2017

WF Subject: OS assignment. KEI & UACT write about the prostate cancer drug, Xtandi (enzalutamide). Asks the Government to reconsider the decision not to use the 'march-in' rights, under the Bayh-Dole Act, for this excessively-priced drug. (AS-760889)

IC: od_osp

From: Goldman, Andrew

To: Price, TomMattis, Jim

Remarks: b5

b5

b5

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 4/20/2017 1:51:59 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wolinetzcdc9a]; Lauer, Michael (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=recipients/cn=lauerm]; Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]; McGarey, Barbara (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=MCGAREYB]; Tabak, Lawrence (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=nidcr/cn=tabakl]; Berkley, Dale (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=BERKLEYD]; Berkson, Laura (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Damianold]; Myles, Renate (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=recipients/cn=mylesr]
Subject: Fwd: KEI petitions HHS/ DOD (again) for Xtandi march in
Attachments: KEI petition on Xtandi to Trump DOD.pdf

Sent from my iPhone
>

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 1/19/2017 3:17:38 AM
To: Gottesman, Michael (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=GottesmM]; Wolinetz, Carrie (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wolinetzcdc9a]; Kassilke, Deborah (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=od/cn=kassilke]; Culhane, Ned (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=recipients/cn=culhane]; Berkson, Laura (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Damianold]; Dodson, Sara (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Dodsonse]; Hsiao, Timothy (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Hsiaoht9d1]; Jorgenson, Lyric (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=recipients/cn=jorgensonla]
CC: McBurney, Margaret (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=cc/cn=mmcurney]
Subject: Fwd: KEI alleges patent failed to disclose NIH funding

Sent from my iPhone

Begin forwarded

Seen this:

From PatentlyO

Bayh-Dole Act: Failing to Disclose Government Funding

January 18, 2017Dennis Crouch

Interesting filing from the folks at KEI. That alleges IONIS Pharma (formerly ISIS) and Cold Springs Harbor Labs failed to disclose Federal funding supported development of the inventions underlying their patents covering nusinersen and its for the treatment of spinal muscular atrophy (SMA). See U.S. Patent Nos. 8,361,977 and 8,980,853.

The **Bayh-Dole Act** allows private entities to patent inventions developed through federal funding. However, the law requires that the federal funding be disclosed in order to allow the Government to understand and exercise its corresponding rights.

An entity that fails to disclose the funding is then subject to the penalty of title being awarded to the U.S. government – although the Government must demand title. “The Federal Government may receive title to any subject invention not disclosed to it within such time.” 35 U.S.C. § 202(c)(1).

The KEI filing is in the form of a letter to Inspector General of HHS (parent of NIH) asking for an investigation and action.

Read the Filing: [\[18jan2017-oig-investigation-request-nusinersen-patents\]](#)

If the new Trump Administration is serious about high drug prices, this may be a place to start. Nusinersen is priced at \$750,000 for the first year of treatment and \$375,000 for every year thereafter.

-

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 12/22/2016 1:48:53 AM
To: Carr, Sarah (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=CARRS]
Subject: Re: Clinical data policy

Thanks

Sent from my iPhone

On Dec 21, 2016, at 8:16 PM, Carr, Sarah (NIH/OD) [E] <CarrS@OD.NIH.GOV> wrote:

Mark,

Just getting back to you about whether KEI commented on the NPRM or draft NIH policy. I searched the regs.gov docket for the rule and the public comments that were submitted to us on the policy and didn't find anything from KEI.

Sarah

From: Carr, Sarah (NIH/OD) [E]
Sent: Tuesday, December 20, 2016 8:04 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Paltoo, Dina (NIH/OD) [E] <paltood@od.nih.gov>
Subject: RE: Clinical data policy

Mark,

I spose

b5

b5

Sarah

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, December 20, 2016 2:28 PM
To: Carr, Sarah (NIH/OD) [E] <CarrS@OD.NIH.GOV>; Paltoo, Dina (NIH/OD) [E] <paltood@od.nih.gov>
Subject: RE: Clinical data policy

b5

From: Carr, Sarah (NIH/OD) [E]
Sent: Tuesday, December 20, 2016 2:08 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Paltoo, Dina (NIH/OD) [E] <paltood@od.nih.gov>
Subject: RE: Clinical data policy

Mark, can you say more about NIST's draft regs that KEI was commenting on or send a link? And

[b5]
[b5] Sarah

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, December 20, 2016 1:56 PM
To: Paltoo, Dina (NIH/OD) [E] <paltood@od.nih.gov>; Carr, Sarah (NIH/OD) [E] <CarrS@OD.NIH.GOV>
Subject: Clinical data policy

Dina and Sarah:

NIST received a public response to draft regs from KEI that includes the following [b5]

[b5]
Suggestions for [b5]

In order to develop more useful evidence to evaluate licensing policies, licenses could and should require transparency of the costs of research and development. For medical inventions, this should include an annual report for R&D outlays, with the company reporting the

following information for each clinical trial that it conducts on the patented invention:

- a. ClinicalTrials.Gov identifier;
- b. Phase;
- c. Conditions;
- d. Interventions;
- e. Title Acronym/Titles;
- f. Outcome Measures;
- g. Sponsor/Collaborators;
- h. Other Study IDs;
- i. Expenditures (for that year);

Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer
Director, Division of Technology Transfer and Innovation Policy
Office of Science Policy
Office of the Director
National Institutes of Health

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHExchange/CN=OD/CN=ROHRBAUM]
Sent: 12/20/2016 1:58:07 AM
To: Myles, Renate (NIH/OD) [E] [/O=NIH/OU=NIHExchange/cn=recipients/cn=mylesr]
Subject: Re: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

b5

Sent from my iPhone

On Dec 19, 2016, at 7:48 PM, Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov> wrote:

Haven't read it yet, but wanted you to take a look. I'll share more broadly when I'm home.

Health

Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

By MATT RICHTEL and ANDREW POLLACK DEC. 19, 2016

<image001.jpg>

Dr. Steven Rosenberg, left, who has led the surgery branch at the National Cancer Institute for 42 years, and Dr. Arie Belldegrun, the founder of Kite Pharma. Credit Jesse Dittmar (left) and Emily Berl (right) for The New York Times

Enthusiasm for cancer immunotherapy is soaring, and so is Arie Belldegrun's fortune.

Dr. Belldegrun, a physician, co-founded Kite Pharma, a company that could be the first to market next year with a highly anticipated new immunotherapy treatment. But even without a product, Dr. Belldegrun has struck gold.

His stock in Kite is worth about \$170 million. Investors have profited along with him, as the company's share price has soared to about \$50 from an initial price of \$17 in 2014.

The results reflect widespread excitement over immunotherapy, which harnesses the body's immune system to attack cancer and has rescued some patients from near-certain death. But they also speak volumes about the value of Kite's main scientific partner: the United States government.

Kite's treatment, a form of immunotherapy called CAR-T, was initially developed by a team of researchers at the National Cancer Institute, led by a longtime friend and mentor of Dr. Belldegrun. Now Kite pays several million a year to the government to support continuing research dedicated to the company's efforts.

The relationship puts American taxpayers squarely in the middle of one of the hottest new drug markets. It also raises a question: Are taxpayers getting a good deal?

Defenders say that the partnership will likely bring a lifesaving treatment to patients, something the government cannot really do by itself, and that that is what matters most.

Critics say that taxpayers will end up paying twice for the same drug — once to support its development and a second time to buy it — while the company reaps the financial benefit.

"If this was not a government-funded cancer treatment — if it was for a new solar technology, for example — it would be scandalous to think that some private investors are reaping massive profits off a taxpayer-funded invention," said James Love, director of Knowledge Ecology International, an advocacy group concerned with access to medicines.

Photo

<image002.jpg>

Dr. Rosenberg and Dr. Belldgrun in the mid-1980s. Dr. Belldgrun became a research fellow for Dr. Rosenberg at the cancer institute in 1985. Credit Kite Pharma

The debate goes squarely to one of the nation's most vexing challenges: rising health care and drug prices. Kite is one of a growing number of drug and biotech companies relying on federal laboratories. Analysts expect the company to charge at least \$200,000 for the new treatment, which is intended as a one-time therapy for patients.

While the law allows the government to demand drug-price concessions from its private-sector partners, the government has declined to do so with Kite and generally disdains the practice. Insisting on lower prices, federal researchers say, would drive away innovative partners that speed the drug-development process and benefit patients. But with the government doing so much pivotal research, others say that the private sector cannot afford to walk away.

"The market is so reliant on the knowledge and know-how that comes out of the government and academic labs," said Dr. Aaron Kesselheim, director of the Program on Regulation, Therapeutics and Law at Brigham & Women's Hospital in Boston.

Price curbs, he said, "would not suddenly lead to a total abandonment of this pipeline. It couldn't possibly."

Drug makers would be especially unlikely to turn away from immunotherapy, where the promising science has set off a "gold rush mentality," according to Mark Edwards of Bioscience Advisors, a company which tracks pharmaceutical licensing deals.

The National Institutes of Health, the parent agency of the National Cancer Institute, currently has about 400 cooperative research agreements with companies, and licenses hundreds of patented inventions for private-sector development.

Kite executives and national health officials characterize their partnership as a model arrangement in a system established by Congress three decades ago. The system has given birth to the cancer drug Taxol, the AIDS drug Prezista, two cervical cancer vaccines and a widely used test for H.I.V. infection, among other innovations.

Continue reading the main story

Photo

<image003.jpg>

Dr. Rosenberg in his lab at the cancer institute in Bethesda, Md. Partnerships between government labs and drug companies are "absolutely essential or many discoveries will not see the light of day," he said. Credit Jesse Dittmar for The New York Times

Kite's first drug, called KTE-C19, could help thousands of patients each year in the United States with certain blood cancers. If it succeeds, it could generate sales of \$1 billion to \$2 billion annually, according to Wall Street analysts, making it among the most lucrative drugs to come from government research.

But the government's share of any Kite success would be modest, much lower than some academic research groups have wrangled in immunotherapy deals worth hundreds of millions of dollars. Federal officials counter that the reward to the taxpayer is not money but the drug itself. "This is exactly the way things should work," said Dr. Steven Rosenberg, who has led the surgery branch at the National Cancer Institute for 42 years and led development of Kite's drug. Such partnerships, he said, are "absolutely essential or many discoveries will not see the light of day."

Moreover, government officials say, companies in such deals must take significant financial risks and expenditures on their own, without any guarantee that the drug will be approved.

Kite says it has spent more than \$200 million on research and development, including running larger clinical trials than those conducted by the cancer institute, and recently spent about \$30 million to build a factory that will be able to make treatments for up to 5,000 patients a year.

Setting the price of the drug, Dr. Rosenberg said, "is for the marketplace."

A Public-Private Partnership

Like many business deals, this one began with a personal relationship — in this case between Dr. Rosenberg and Dr. Belldgrun.

After finishing medical school in his native Israel, performing surgery in helicopters for the Israeli armed forces, and completing residency at Brigham & Women's Hospital, Dr. Belldegrun became a research fellow for Dr. Rosenberg at the N.C.I. It was 1985, and Dr. Belldegrun was put to work on a new project of Dr. Rosenberg's — extracting tumor-fighting immune cells from cancer patients, multiplying them in the laboratory, and putting them back in. "He was one of the more outstanding fellows to come through," said Dr. Rosenberg, 76, who is widely considered a cancer research luminary.

[Continue reading the main story](#)

Photo

<image004.jpg>

Dr. Belldegrun, center, at the Nasdaq stock exchange, where Kite Pharma is listed. The company was founded in 2009 and went public in 2014. Credit Nasdaq, 2016

When the fellowship ended in 1988, Dr. Belldegrun became a prominent surgeon at the University of California, Los Angeles, but the two men stayed in touch. Eventually, Dr. Belldegrun, 67, got the entrepreneurial bug. He co-founded a biotech company, Agensys, which was acquired by a bigger company for more than \$500 million. He was also involved with Cougar Biotechnology, which developed the prostate cancer drug Zytiga and was acquired by Johnson & Johnson for \$1 billion in May 2009. A month later, Dr. Belldegrun formed Kite with a group of colleagues and investors to pursue cancer immunotherapy.

That same month, a Florida marine contractor named Eric Karlson, whose non-Hodgkin's lymphoma was advancing despite four prior treatments, became the first patient treated by Dr. Rosenberg with what would eventually become KTE-C19. The treatment entailed removing some of Mr. Karlson's immune system T cells from his blood, genetically engineering them to recognize and fight his cancer, multiplying the T cells to huge numbers in the laboratory and transferring them back into his body. After two such treatments, Mr. Karlson remains alive and cancer-free eight years later.

Kite initially thought it would pursue an approach to immunotherapy known as cancer vaccines, but in 2010, Dr. Belldegrun visited Dr. Rosenberg and was shown the X-rays of Mr. Karlson and of a second patient.

Dr. Belldegrun was bowled over. "I had no doubt that this is going to be a drug and, more than that, it will become a platform for multiple products," he recalled. "We never looked back." Over the next two years, the National Cancer Institute worked out a deal with Kite that was signed in 2012. It was the first of eight contracts between the government and the company that generally take two forms.

In one type of contract, Kite licenses patented inventions and agrees to pay the government royalties, roughly 5 percent of sales of any commercial product arising from a particular patent. However, there is no such license specifically for KTE-C19 because the underlying treatment was not patented by the N.C.I., so royalties will be minimal.

Officials say the agency did not apply for a patent because the treatment was similar to what others had been developing. Also, at the time the treatment was first created, in 2007, immunotherapy was considered to have dim commercial prospects.

"Back then, we didn't even think about commercial aspects," said Dr. James N. Kochenderfer, a scientist at the agency who designed the treatment when working in Dr. Rosenberg's group.

Under the second type of contract, known as a cooperative research and development agreement, Kite provides money to the N.C.I. to support research. Kite is now paying \$3 million a year to Dr. Rosenberg's lab and has provided \$7.5 million to it in total since 2012. Based on its regulatory filings, Kite is paying \$7.8 million a year for research agreements and licenses in total, with at least \$4 million of that going to the cancer institute and the rest to academic or corporate partners.

The taxpayer has invested, too. Dr. Rosenberg estimated that the government has spent roughly \$10 million over the years on what has become KTE-C19. He said Kite's \$3 million a year is about equal to the taxpayer funding in that area and has helped speed research.

These days, researchers from Kite and the cancer institute, typically including Dr. Rosenberg and Dr. Beldegrun, confer by conference call every other Thursday for 90 minutes. Kite employees have spent long periods at the N.C.I., learning how to manufacture the therapy and how to treat patients in advance with chemotherapy.

"We shouldn't underestimate the value and the importance of N.I.H., not only to Kite but to the whole field of engineered T-cell therapy," Dr. Beldegrun said. When Kite signed its first deal with the cancer agency, he said, it "tapped into six years of monumental work that they had done."

Some immunotherapy competitors marvel at the company's coup in tapping into the agency's expertise. "They got 20 years of research all together in one scoop," said Dr. Carlos Paya, chief executive of Immune Design, which is pursuing a different approach.

But government officials say few, if any, other companies were interested in the technology at the time Dr. Beldegrun came calling. Dr. Rosenberg said that before Kite, a few companies, including Johnson & Johnson, had looked at an earlier version of his technology but were wary because treatment involved processing each patient's cells.

Government-developed technology available to be licensed to companies is posted on the website of the National Institutes of Health. And when the agency intends to grant a license to a particular company, it publishes that in the Federal Register, inviting public comment and possible competing offers. Both steps were taken in the case of Kite, officials said.

Kite did not get everything the cancer institute has developed in the field. Some other companies, including Opus Bio and Bluebird Bio, got rights to some products, in part because the companies had special expertise that the agency's researchers desired. But Kite seems to have gotten the balance of them and N.C.I. technology accounts for the majority of its pipeline of possible products, though the company is diversifying.

Photo

<image005.jpg>

A slide that Kite Pharma used in presentations to potential investors pointed out the company's relationship with Dr. Rosenberg.

Dr. Rosenberg professes no interest in the business side of the Kite relationship. He does not own stock in any company, even Kite, though he could get up to \$150,000 a year in patent royalties if some of Kite's efforts pay off.

Dr. Beldegrun, in contrast to his mentor, has commercial flair. He is known for his sharp business suits, lives in the Bel-Air neighborhood of Los Angeles, and seems as comfortable on Wall Street or in high society as in the operating room.

Kite's relationship with the N.C.I. is an important part of its appeal to investors. In some presentations, Dr. Beldegrun has shown a photograph of himself with Dr. Rosenberg in their younger days. And he persuaded Dr. Rosenberg to speak at Kite's first big meeting for investors in June 2015, the only time he has ever spoken to Wall Street.

In emails obtained through a Freedom of Information Act request by Knowledge Ecology International, Dr. Beldegrun praised Dr. Rosenberg's talk and sent him copies of investment reports from the conference written by Wall Street analysts.

"Thank you for making the effort to come to NY," Dr. Beldegrun wrote. "I heard only raving reviews about your presence and presentation."

A 'Reasonable' Question

The reliance of private companies on government-funded research goes well beyond obvious cases like Kite. In many instances, companies work with universities or medical centers that, in turn, have been funded from the \$32 billion annual budget of the National Institutes of Health. Kite's two main competitors, Novartis and Juno Therapeutics, for instance, derived similar immunotherapy treatments largely from academic institutions, developed at least in part with

government funding. Novartis has a relationship with the University of Pennsylvania, and Juno with the Memorial Sloan Kettering Cancer Center, the Fred Hutchinson Cancer Research Center and Seattle Children's Hospital.

"For the most important drugs you'll see some public-sector involvement," said Bhaven Sampat, an associate professor of health policy and management at Columbia University. He was one author of a study that found that 9 percent of all drugs approved between 1988 and 2005 were based directly on a patent held by the public sector. But 47.8 percent of the drugs relied at least indirectly on some federally funded research.

Continue reading the main story

Photo

<image006.jpg>

Eric Karlson at his home on Marco Island, Fla., this month. Mr. Karlson's non-Hodgkin's lymphoma was successfully treated by Dr. Rosenberg with what would eventually become KTE-C19. Credit Scott McIntyre for The New York Times

The figures were higher for more medically important drugs: 17.4 percent had a direct public-sector patent, while 64.5 percent had at least an indirect public-sector influence.

These figures are up sharply from before the 1980s. Such partnerships and licensing deals were encouraged by the 1980 Bayh-Dole and Stevenson-Wydler Acts, and the 1986 Federal Technology Transfer Act. The laws are credited with jump-starting the biotechnology industry. But from the beginning, some people questioned whether taxpayers were getting a bad deal. Perhaps the best-known drug developed from a cooperative research and development agreement — the cancer drug Taxol — was the subject of several congressional hearings in the early 1990s that investigated whether the drug's maker, Bristol-Myers Squibb, charged too much and whether the government recouped enough of its investment. In the end, the pricing was left unchanged.

The N.I.H. argues that if it imposes pricing restrictions, it won't get partners. In fact, in 1995, it struck from its negotiating tactics a goal that prices be "reasonable."

"Companies will not take technologies from us if we say the government will decide in the future what the price will be," said Mark Rohrbaugh, who ran the technology transfer office at the institutes from 2001 to 2013 and is now an adviser to the agency. After the "reasonable price" clause was struck, he said, there was a threefold increase in partnership deals.

The N.I.H. can collect royalties from successful products to help offset the costs of the research, but so far these royalties have been small, amounting to an estimated \$135 million in the last fiscal year from 870 licenses, with the bulk of the money coming from a small number of drugs. "We're not preoccupied with financial value," Dr. Rohrbaugh said. "Our mission is treatment of people and improving public health."

In that regard, the government's bet on a small company like Kite, which might have seemed risky, appears to be paying off so far. Dr. Belldegrun has largely delivered on promises to raise money, assemble an experienced staff, build the factory, conduct clinical trials and begin to apply for regulatory approval. Once considered the underdog to Novartis and Juno, Kite might be the first reach the market.

Photo

<image007.jpg>

Scans of Mr. Karlson's body before and after his treatment. In the cross-sections on the left, the arrows point to signs of lymphoma in areas such as his armpits, chest, spleen and pelvis. Credit National Cancer Institute

Academic centers and companies often drive harder bargains in licensing technology. In some cases, academic centers own a stake in a company they license technology to, allowing them to reap a financial windfall if the company does well. Both the Hutchinson cancer center and Sloan

Kettering have owned stock in Juno and are entitled to substantial payments — up to \$350 million and \$150 million — if Juno’s stock reaches certain levels.

The N.I.H. does not take equity positions in companies to avoid an appearance of a conflict of interest. So to critics of the government deals, drug prices are crucial to understanding taxpayer value. After all, they ask, is a drug truly widely available — which is what the government says is its measure of success — if it costs too much for some people?

Rachel Sachs, an associate law professor at Washington University in St. Louis and expert in innovation policy, said the government had every right to seek price concessions. She noted that the government, through Medicare and Medicaid, was effectively buying its inventions back from itself. “The public is paying for the research and to the extent that many people, if not most, will pay through public insurance, we’re paying again,” she said.

Hillary Clinton, in her campaign for president, promised to set new rules for federal support of research so that Americans “get the value they deserve” for the money taxpayers spend in supporting research. It is not clear how President-elect Donald J. Trump will approach these issues; he has said he favors reducing health care costs, but Republicans, who control Congress, too, have opposed government involvement in price setting.

One mechanism to control pricing already exists. It is called march-in rights, and it lets the N.I.H. take back control of a patent on an invention made with federal funding if the drug is not being made available to the public on reasonable terms. The tool has gone unused.

Earlier this year, Knowledge Ecology International and another advocacy group, the Union for Affordable Cancer Treatment, petitioned the agency to exercise march-in rights on Xtandi, a prostate cancer drug that was developed by federally funded researchers at U.C.L.A. It said the price in the United States of about \$129,000 a year, two to four times that in other developed countries, meant the drug was not reasonably available. The effort was supported by other public interest groups and some Democratic members of Congress.

U.C.L.A. made more than \$500 million by selling its royalty rights to the drug. But the N.I.H. declined to exercise its march-in rights on Xtandi, arguing that it was not qualified to judge whether a drug’s price is reasonable and that a high price does not mean a drug is not being made available to the public.

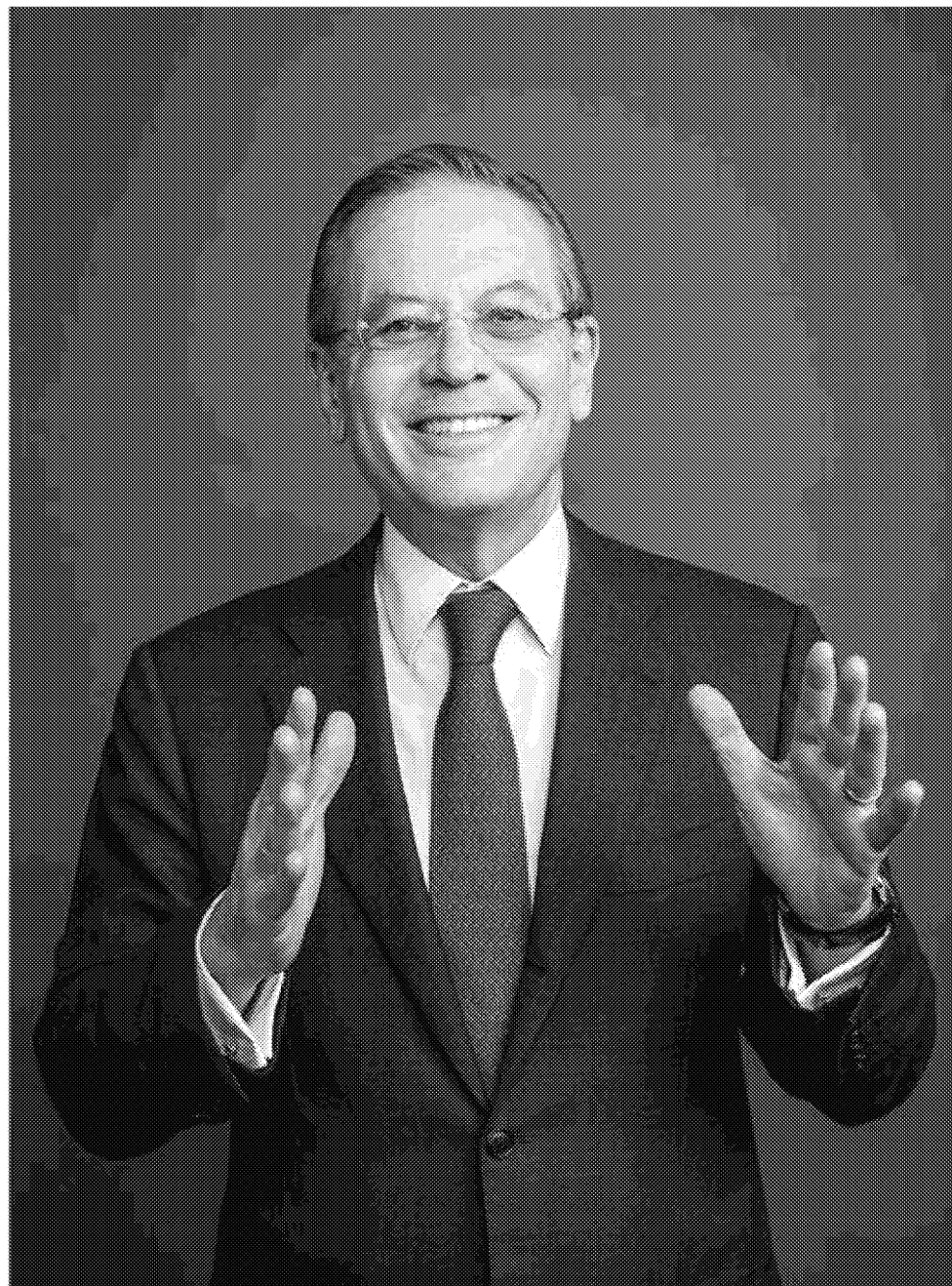
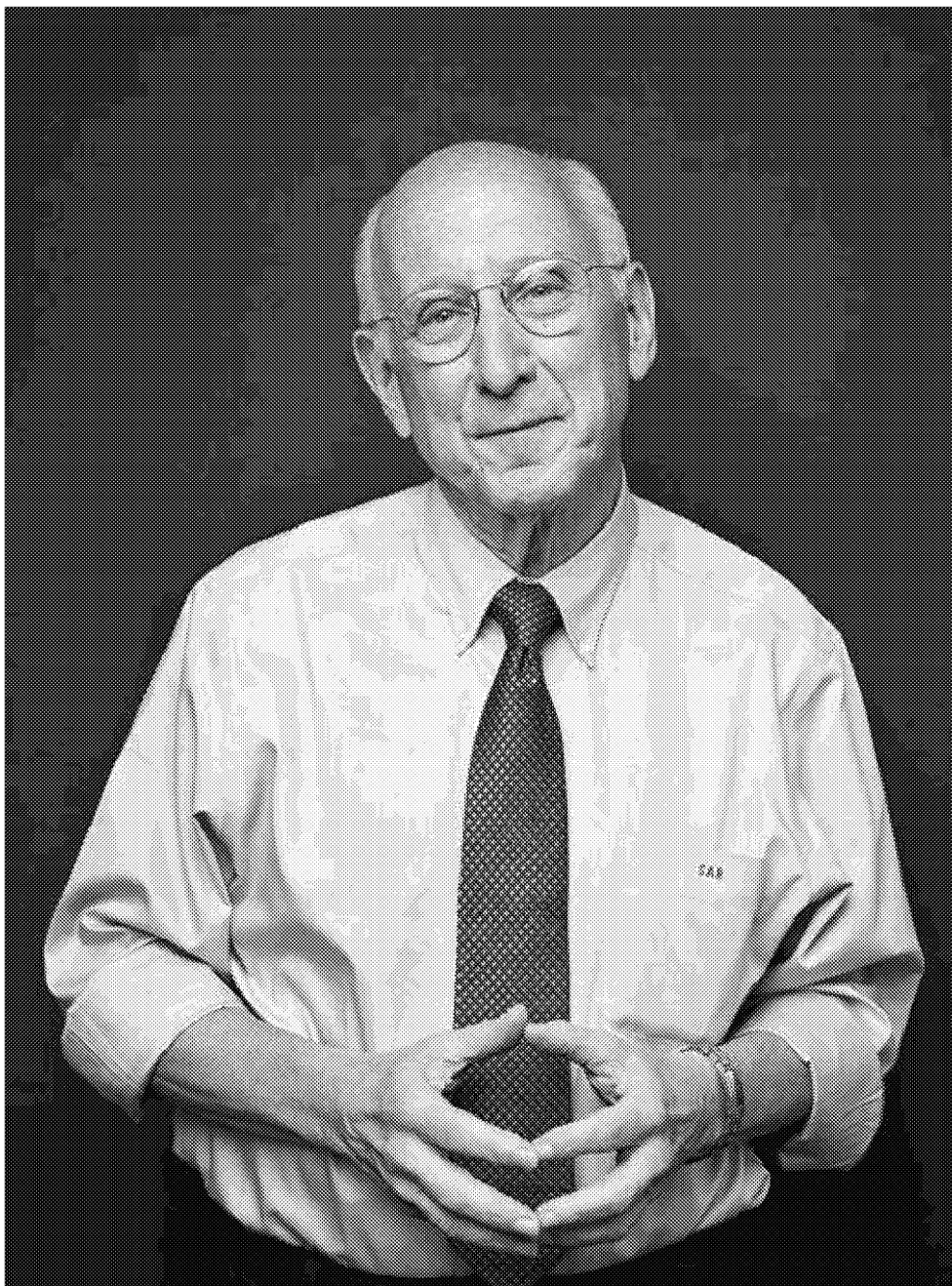
“N.I.H. has made it clear that its job is not to decide prices of drugs, period,” Dr. Rohrbaugh said. Kite says it has not decided what to charge for KTE-C19, but Dr. Belldegrun hinted that Kite’s therapy might be relatively expensive because ideally it would be a single treatment that would cure the patient, not a drug that would have to be taken continuously. He added that Kite would take steps to make sure that everyone who needed the drug could get it.

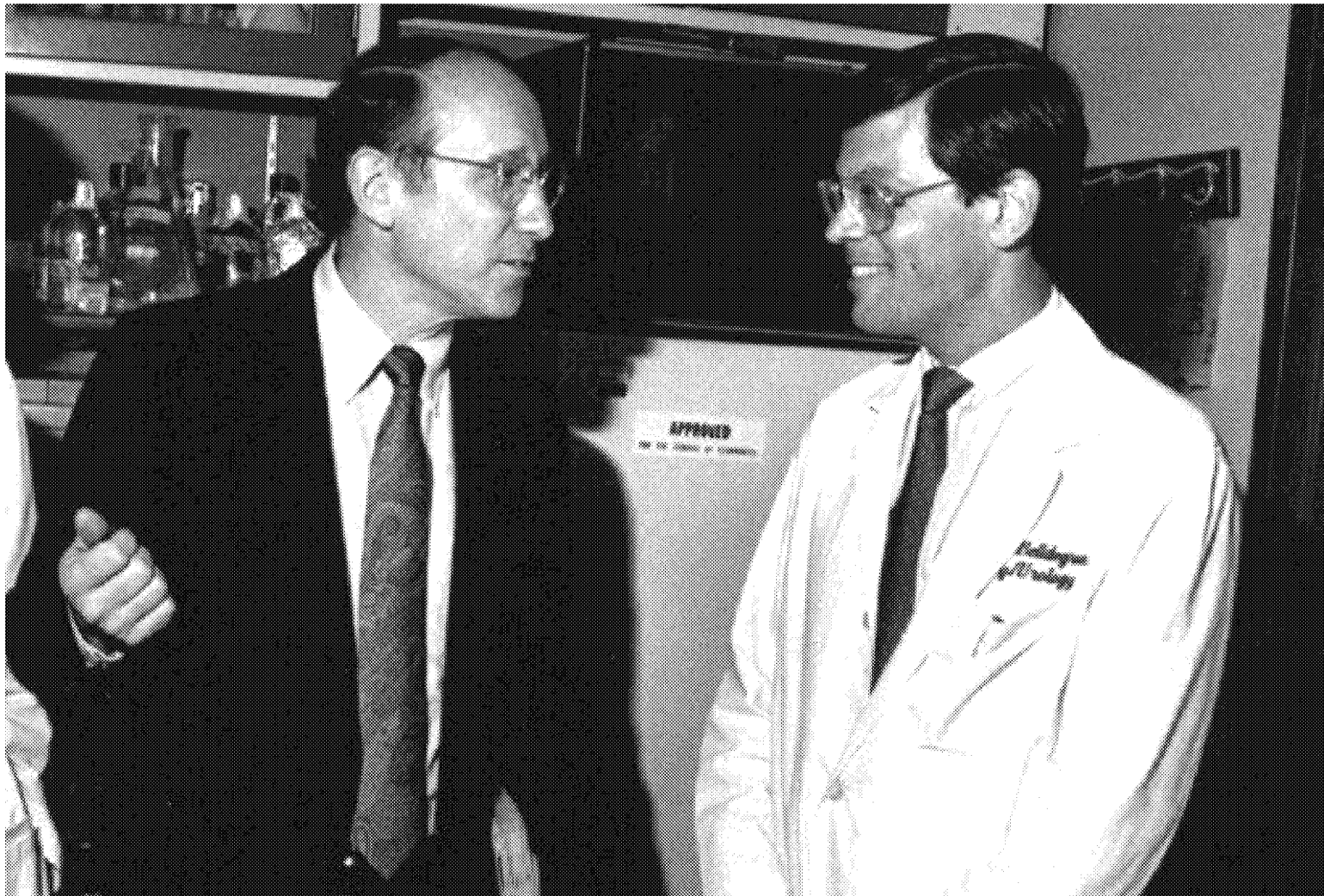
Meantime, the relationship between Kite and the National Cancer Institute is expanding to develop treatments for other cancers, including one technique Dr. Rosenberg thinks could be used to attack solid tumors like colon, breast and lung cancer.

“The potential for broad applicability is huge,” he said.

That could mean many lives saved and maybe more billion-dollar drugs for Kite and its investors, with the American taxpayer right in the middle of the deal.

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Building a Robust IP Estate with Scientific Leaders in Gene-Based Cellular Immunotherapy

Clinical Pioneer



Steven Rosenberg, MD, PhD

- Chief of Surgery, NCI
- Professor of Surgery, Uniformed Services University of Health Sciences and George Washington University School of Medicine and Health Sciences

Inventors



Margo R. Roberts, PhD

- Chief Scientific Officer, Kite Pharma, Inc.
- Inventor on 16 US patents and patent applications related to CAR T cell technology and tumor vaccine therapies



Zelig Eshhar, PhD

(Member, Kite Scientific Advisory Board)

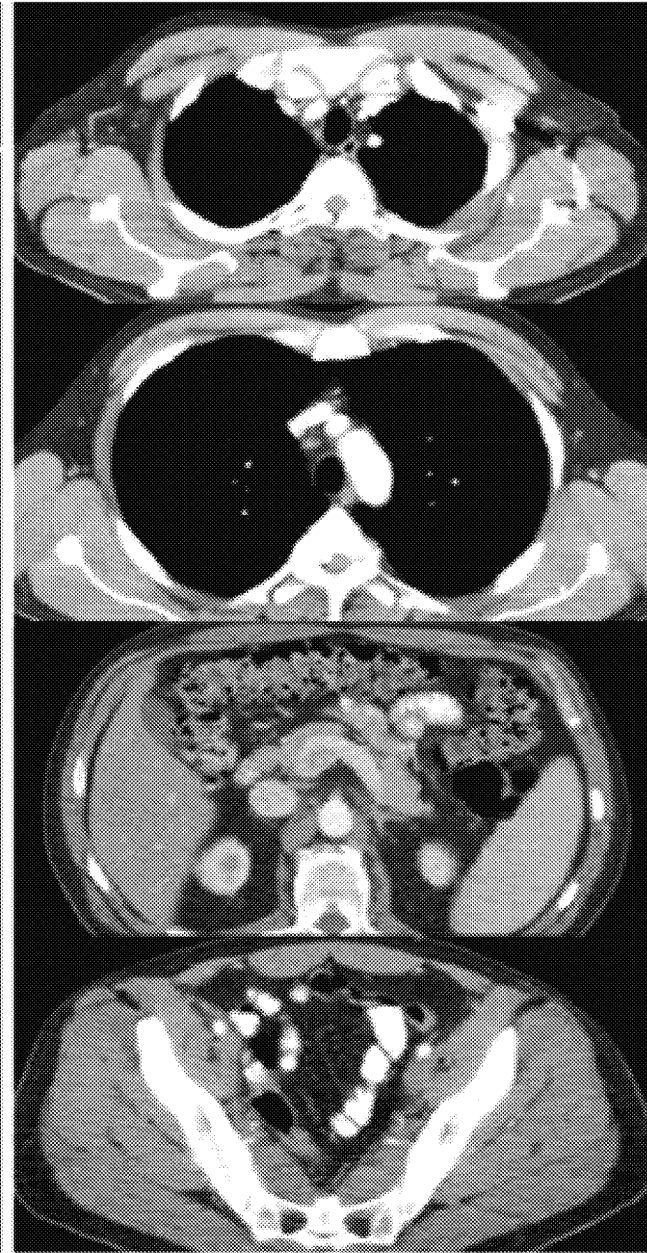
- Chairman of Immunology Research, Sourasky Medical Center, Tel Aviv
- Professor Emeritus, Weizmann Institute of Science, Israel



lymphoma



June 2, 2009



March 14, 2012

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 11/7/2016 2:26:40 PM
To: Fine, Amanda (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Fineab]; Myles, Renate (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=recipients/cn=mylesr]
Subject: Fwd: time sensitive request: talking points for today's xtandi meeting

Do you have any talking points handy on the Xtandi march-in?

Sent from my iPhone

Begin forwarded message:

From: "Baker, Rebecca (NIH/OD) [E]" <bakerrg@od.nih.gov>
Date: November 7, 2016 at 9:18:48 AM EST
To: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Cc: "Wolinetz, Carrie (NIH/OD) [E]" <carrie.wolinetz@nih.gov>
Subject: time sensitive request: talking points for today's xtandi meeting

Hi Mark,

Update on today's meeting with KEI:

Barb won't be joining and it will be just you, me, and Kathy.

b5

Thanks,
Rebecca

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 6/8/2016 12:16:23 AM
To: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: Fwd: Use Bayh Dole to Lower Drug Prices
Attachments: Nature Medicine FINAL.pdf; ATT00001.htm

Sent from my iPhone

Begin forwarded message:

From: "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>
Date: June 7, 2016 at 8:14:37 PM EDT
To: "Hudson, Kathy (NIH/OD) [E]" <Kathy.Hudson@nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" <Lawrence.Tabak@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" <carrie.wolinetz@nih.gov>, "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>, "McGarey, Barbara (NIH/OD) [E]" <MCGAREYB@od.nih.gov>
Subject: FW: Use Bayh Dole to Lower Drug Prices

FYI

From: Alfred Engelberg [<mailto:aengelberg@nqlbrq.com>]
Sent: Tuesday, June 07, 2016 6:23 PM
To: Alfred Engelberg
Subject: Use Bayh Dole to Lower Drug Prices

I thought you would be interested in this Opinion piece that was published in Nature Medicine online today.

Alfred Engelberg
aengelberg@nqlbrq.com

REL0000024705

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 5/4/2016 1:29:59 PM
To: Lambert, Richard (NIH/NIAID) [C] [/O=NIH/OU=NIHEXCHANGE/cn=NIAID/cn=LAMBERTR]
Subject: Re: [Ip-health] 'Government Patent Use': A Legal Approach to Reducing Drug Spending

Thanks

Sent from my iPhone

> On May 4, 2016, at 9:24 AM, Lambert, Richard (NIH/NIAID) [C] <lambertr@niaid.nih.gov> wrote:
>
> Hi Mark. I sent this to Dale and he suggested you might be interested. So here you are!
> Dick
>
> Richard A. Lambert
> Contractor
> National Institute of Allergy and Infectious Diseases
> National Institutes of Health
> U.S. Department of Health and Human Services
> 5601 Fishers Lane, Rm. 2G47, MSC 9804
> Bethesda, MD 20892-9804
> (Courier: Rockville, MD. 20852)
> 301.496.2644 main officeline
> 240.627.3706 direct line
> FAX 240.627.3117
> lambertr@niaid.nih.gov
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accept liability for any unauthorized statements made by the sender in this message.
>
> -----Original Message-----
> From: Lambert, Richard (NIH/NIAID) [C]
> Sent: Wednesday, May 04, 2016 7:32 AM
> To: Berkley, Dale (NIH/OD) [E]
> Subject: FW: [Ip-health] 'Government Patent Use': A Legal Approach to Reducing Drug Spending
>
> Another take on 1498
>
> Richard A. Lambert
> Contractor
> National Institute of Allergy and Infectious Diseases National Institutes of Health U.S. Department of
Health and Human Services
> 5601 Fishers Lane, Rm. 2G47, MSC 9804
> Bethesda, MD 20892-9804
> (Courier: Rockville, MD. 20852)
> 301.496.2644 main officeline
> 240.627.3706 direct line
> FAX 240.627.3117
> lambertr@niaid.nih.gov
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receive this message in error please inform the sender and delete it immediately from your mailbox or any
other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not
accept liability for any unauthorized statements made by the sender in this message.
>
> -----Original Message-----
> From: Jamie Love [mailto:james.love@keionline.org]
> Sent: Tuesday, May 03, 2016 8:26 PM
> To: Kapczynski, Amy
> Cc: ip-health
> Subject: Re: [Ip-health] 'Government Patent Use': A Legal Approach to Reducing Drug Spending
>
> Amy,
>
> Sorry if I sound too negative on the compensation issues. I agree with you, that there is some good
case law, and I also agree that the executive branch should test the law, particularly in cases where
better options at not available, or where the government could not do worse. Just raising the issue in

REL0000024709

the Cipro case was sufficient to make the negotiations on the price quite favorable. But test cases can also take a while to work their way through the appeals court, so there is that too. But, since doing nothing is the worst option for a number of scenarios, good that you and Aaron focus attention on this, as another mechanism that should be used.

>
> Jamie

>
>
>
>
>
> On Tue, May 3, 2016 at 11:22 PM, Kapczynski, Amy <amy.kapczynski@yale.edu>
> wrote:

>>
>> Yes, but I don't think the uncertainty is as bad as you suggest here
>> -there is strong caselaw suggesting lost profits are inappropriate,
>> meaning that the courts would reject the idea that a company was
>> entitled to full price. And, even if a court went with lost profits,
>> caselaw requires the company to show that the profits were likely to
>> accrue. In a case like this, where there is significant rationing
>> happening, I don't think the company could show that at their patented
>> price, the expanded sales would have been likely to occur. That's why
>> I think there's a very strong case that the gov almost certainly
>> wouldn't be worse off. And of course, one way to test the waters
>> would be to use the power for a particular population (how about the
>> Indian Health Service, where the new hep C drugs aren't even on the
>> formulary because of their price), and see what negotiations, or a
>> court, would lead to. The gov could limit exposure by picking a set
>> number of doses, given whatever its own lawyers thought its risk would be.
>> In other words, the law is on the gov's side in some important ways,
>> and there are easy ways to proceed w/o big downside liability.
>>
>> Should also say - as we do in the papers - that all of this work is
>> very indebted both to the attention that Jamie, and the Sanders team
>> have done to bring attention to the possibility of using 1498.

>>
>> Amy
>>
>> On May 3, 2016, at 5:04 PM, Jamie Love <james.love@keionline.org> wrote:

>>
>> The uncertainty over the compensation is uncertainly about how much less
>> the government would pay when using 28 USC 1498. If the government use of
>> the product is insensitive to the price, then 28 USC 1498 is more
>> appealing, because you would have bought the product anyway, at a high
>> price. But if you intend to use it more intensively if the price is
>> lower, such as treating everyone who has HCV, rather than patients
>> with advanced disease, or stockpiling Cipro, then the compensation
>> becomes a risk to consider. Having read a lot of 1498(a) cases, the
>> compensation is hard to predict. I agree that the rules for the
>> government have some attractive features, but depending upon the
>> context and the judge, there can be some unpleasant surprises too.

>>
>> Jamie
>>
>> On Tue, May 3, 2016 at 10:46 PM, Kapczynski, Amy
>> <amy.kapczynski@yale.edu>
>> wrote:

>>
>>>
>>> Agree that legislation that clarified the appropriate level of
>>> compensation would be very beneficial. A test case could also
>>> establish more certainty.
>>>
>>> But I don't think there's any way that the gov would be worse off
>>> employing this statute than it would be if it doesn't - there is
>>> strong caselaw rejecting the lost profits approach here, meaning
>>> companies can only obtain a reasonable royalty. Even if a court
>>> rejected that approach and chose lost profits, those profits would
>>> logically and legally have to be capped at the doses the gov actually
>>> would have bought - i.e., the current spending.

>>>
>>> Btw, I am working on a law review article with some colleagues
>>> describing how we think courts should approach the compensation
>>> question. Would welcome thoughts on that,
>>>
>>> Best
>>> Amy

>>>
>>>
>>> On May 3, 2016, at 4:29 PM, Jamie Love <james.love@keionline.org> wrote:
>>>
>>> Our own take on 28 USC 1498 is that it can be useful, but it is not
>>> necessarily well suited for dealing with drug patent cases, given the
>>> case law on compensation to patent holders, which includes
>>> uncertainty on what can be big ticket items.
>>>
>>> If 28 USC 1498 is what you have to work with, you use it. Al
>>> Engelberg and others proposed this in 2001 for Ciprofloxacin, and we
>>> supported that effort then.
>>> (http://www.cptech.org/ip/health/cl/cipro/
>>> <https://urldefense.proofpoint.com/v2/url?u=http-3A__www.cptech.org_ip_health_cl_cipro_&d=AwMFaQ&c=-
dg2m7zwuUDZ0MUCv7Sdqw&r=-ddH8Zceq1hAY-PYLwKNHeKcPT90K3Kb_YdJ7DDd_Uo&m=MPw9Wmrnv4VhfbYbUZwUPhnME7KSUFcM7ifs-biAz9Q&s=PMr-
mbrcm11aOCiB0ymUOqmT29faV20hPyP77L3A-3k&e=>).
>>> 1498 was also used for drugs earlier by DoD.
>>>
>>> When Bernie Sanders proposed that the Department of Veterans Affairs
>>> use
>>> 1498 for HCV drugs, the issue of compensation to Gilead was a concern.
>>> Sanders offered a still to be considered legislative reform that would have
>>> fixed this. Zack Struver did an informative video about the issue here:
>>> https://www.youtube.com/watch?v=xAY4Ua7B2mQ
>>> <https://urldefense.proofpoint.com/v2/url?u=https-3A__www.youtube.com
_>>> _watch-3Fv-3DxAY4Ua7B2mQ&d=AwMFaQ&c=-dg2m7zwuUDZ0MUCv7Sdqw&r=-ddH8Zce
>>> q1hAY-PYLwKNHeKcPT90K3Kb_YdJ7DDd_Uo&m=MPw9Wmrnv4VhfbYbUZwUPhnME7KSUFc
>>> M7ifs-biAz9Q&s=HZO__4HratjmnVcaUYBGRfcl40Cad3x3lynxGxp-A&e=>
>>>
>>> On Tue, May 3, 2016 at 8:04 PM, Kapczynski, Amy
>>> <amy.kapczynski@yale.edu>
>>> wrote:
>>>
>>>>
>>>> Aaron Kesselheim and I just published this in Health Affairs:
>>>> http://content.healthaffairs.org/content/35/5/791.full
>>>> <https://urldefense.proofpoint.com/v2/url?u=http-3A__content.healtha
>>>> ffairs.org_content_35_5_791.full&d=AwMFaQ&c=-dg2m7zwuUDZ0MUCv7Sdqw&r
>>>> =-ddH8Zceq1hAY-PYLwKNHeKcPT90K3Kb_YdJ7DDd_Uo&m=MPw9Wmrnv4VhfbYbUZwUP
>>>> hnME7KSUFcM7ifs-biAz9Q&s=tQq1LY5P8HkR8FTNd0ei6-sdXSxCe_psB0us6f9WR48
>>>> &e=>
>>>>
>>>> Abstract:
>>>>
>>>> The high cost of patent-protected brand-name drugs can strain
>>>> budgets and curb the widespread use of new medicines. An example is
>>>> the case of direct-acting antiviral drugs for the treatment of
>>>> hepatitis C. While prices for these drugs have come down in recent
>>>> months, they still create barriers to treatment. Additionally,
>>>> prescribing restrictions imposed by insurers put patients at
>>>> increased risk of medical complications and contribute to
>>>> transmission of the hepatitis C virus. We propose that the federal
>>>> government invoke its power under an existing "government patent
>>>> use" law to reduce excessive prices for important patent-protected
>>>> medicines. Using this law would permit the government to procure
>>>> generic versions of patented drugs and in exchange pay the
>>>> patent-holding companies reasonable royalties to compensate them for
>>>> research and development. This would allow patients in federal
>>>> programs, and perhaps beyond, to be treated with inexpensive generic
>>>> medicines according to clinical need—meaning that many more patients
>>>> could be reached for no more, and perhaps far less, money than is
>>>> currently spent. Another benefit would be a reduction in the opportunity for companies to extract
monopoly profits that far exceed their risk-adjusted costs of research and development.
>>>>
>>>> Ip-health mailing list
>>>> Ip-health@lists.keionline.org
>>>> http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionlin
>>>> e.org
>>>> <https://urldefense.proofpoint.com/v2/url?u=http-3A__lists.keionline
>>>> .org_mailman_listinfo_ip-2Dhealth-5Flists.keionline.org&d=AwMFaQ&c=-
>>>> dg2m7zwuUDZ0MUCv7Sdqw&r=-ddH8Zceq1hAY-PYLwKNHeKcPT90K3Kb_YdJ7DDd_Uo&
>>>> m=MPw9Wmrnv4VhfbYbUZwUPhnME7KSUFcM7ifs-biAz9Q&s=aXoDFHbdWEQXJ9TSTMXq
>>>> AlVc7jiU-_XFd2zgn0jOMCu&e=>
>>>
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>>> --

```

>>> James Love. Knowledge Ecology International
>>> http://www.keionline.org/donate.html
>>> <https://urldefense.proofpoint.com/v2/url?u=http-3A__www.keionline.or
>>> g_donate.html&d=AwMFaQ&c=-dg2m7zwuudZ0MUcV7Sdqw&r=-ddH8Zceq1hAY-PYLwk
>>> NHeKcPT9OK3Kb_YdJ7DDd_Uo&m=MPw9Wmrmv4VhfbYbUzWUPhnME7KSUFcM7ifs-biAz9
>>> Q&s=z6-brkTwelrwVeKYteJpM9lki1Dsi5o8UNkMdcVnfpY&e=>
>>> KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile:
>>> +41.76.413.6584, twitter.com/jamie_love
>>> <https://urldefense.proofpoint.com/v2/url?u=http-3A__twitter.com_jami
>>> e-5Flove&d=AwMFaQ&c=-dg2m7zwuudZ0MUcV7Sdqw&r=-ddH8Zceq1hAY-PYLwkNHeKc
>>> PT9OK3Kb_YdJ7DDd_Uo&m=MPw9Wmrmv4VhfbYbUzWUPhnME7KSUFcM7ifs-biAz9Q&s=Q
>>> 1UUTA0lc49cYeBgmUH4zj_EVNpbKMsGXhZXBIGoACA&e=>
>>
>> --
>> James Love. Knowledge Ecology International
>> http://www.keionline.org/donate.html
>> <https://urldefense.proofpoint.com/v2/url?u=http-3A__www.keionline.org
>> _donate.html&d=AwMFaQ&c=-dg2m7zwuudZ0MUcV7Sdqw&r=-ddH8Zceq1hAY-PYLwkNH
>> eKcPT9OK3Kb_YdJ7DDd_Uo&m=P9aSSDuS6hAYjQALj3A69yNcovVkpX7ZtCFq2FmnRpc&s
>> =xFqJAGnRb9kQd1PKD2UvB51Mx_rdh9iI1Ts_sFdx1Tk&e=>
>> KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile:
>> +41.76.413.6584, twitter.com/jamie_love
>> <https://urldefense.proofpoint.com/v2/url?u=http-3A__twitter.com_jamie
>> -5Flove&d=AwMFaQ&c=-dg2m7zwuudZ0MUcV7Sdqw&r=-ddH8Zceq1hAY-PYLwkNHeKcPT
>> 9OK3Kb_YdJ7DDd_Uo&m=P9aSSDuS6hAYjQALj3A69yNcovVkpX7ZtCFq2FmnRpc&s=kvhx
>> TM54ai1lWsuwbEALpTB75I-4jb_HoWmKqDvQYyM&e=>
>
>
> --
> James Love. Knowledge Ecology International http://www.keionline.org/donate.html
> KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile:
> +41.76.413.6584, twitter.com/jamie_love
>
> -----
> Ip-health mailing list
> Ip-health@lists.keionline.org
> http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org

```

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/OD/CN=ROHRBAUM]
Sent: 10/30/2016 7:35:13 PM
To: Lambert, Richard (NIH/NIAID) [C] [/O=NIH/OU=NIH/OD/CN=LAMBERTR]
Subject: Re: march-in criteria for circumstances outside US

Not per se

b4,b5

b4,b5

b5

Sent from my iPhone

On Oct 28, 2016, at 8:38 AM, Lambert, Richard (NIH/NIAID) [C] <lambertr@niaid.nih.gov> wrote:

Are there any march in requests currently pending?

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, October 18, 2016 12:10 PM
To: Lambert, Richard (NIH/NIAID) [C]
Subject: RE: march-in criteria for circumstances outside US

b5

From: Lambert, Richard (NIH/NIAID) [C]
Sent: Tuesday, October 18, 2016 11:53 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: march-in criteria for circumstances outside US

I suppose

b5

b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, October 18, 2016 11:47 AM
To: Lambert, Richard (NIH/NIAID) [C]
Subject: Re: march-in criteria for circumstances outside US

He said he was not aware of anything in the leg history that would suggest using it except for US triggers

Sent from my iPhone

On Oct 18, 2016, at 11:43 AM, Lambert, Richard (NIH/NIAID) [C] <lambertr@niaid.nih.gov> wrote:

And Joe Allen would have an opinion

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, October 18, 2016 11:28 AM
To: Lambert, Richard (NIH/NIAID) [C]
Subject: RE: march-in criteria for circumstances outside US

REL0000024713

And Arno and Davis

From: Lambert, Richard (NIH/NIAID) [C]
Sent: Tuesday, October 18, 2016 11:28 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: march-in criteria for circumstances outside US

Mark,
Not that I know of, but it's the sort of thing I'd think Jamie Love would think about.
Dick

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, October 18, 2016 11:10 AM
To: Lambert, Richard (NIH/NIAID) [C]
Subject: march-in criteria for circumstances outside US

Dick:

Without considering some of the particular issues in the news, has anyone ever opined in general on whether march-in provisions apply to meet health and safety or lack of practical application outside the US?

-Mark
Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer
Director, Division of Technology Transfer and Innovation Policy
Office of Science Policy
National Institutes of Health

b4

Best regards,

Ashley

Ashley J. Stevens, D.Phil(Oxon), CLP, RTTP

<image001.jpg>

President

70 Yale Street, Suite 100
Winchester, MA 01890-2331

Tel: (781) 721-2670

Cell: **b6**

astevens@fipgllc.com

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/OD/CN=OD/CN=ROHRBAUM]
Sent: 2/20/2017 9:38:04 PM
To: McGarey, Barbara (NIH/OD) [E] [/O=NIH/OU=NIH/OD/CN=OD/CN=MCGAREYB]
CC: Berkley, Dale (NIH/OD) [E] [/O=NIH/OU=NIH/OD/CN=OD/CN=BERKLEYD]
Subject: Re: Advice

I think we should

b5

b5

Sent from my iPhone

> On Feb 20, 2017, at 2:56 PM, McGarey, Barbara (NIH/OD) [E] <MCGAREYB@od.nih.gov> wrote:

b5

> Sent from my BlackBerry 10 smartphone.
> From: Tabak, Lawrence (NIH/OD) [E] <Lawrence.Tabak@nih.gov>
> Sent: Monday, February 20, 2017 12:52 PM
> To: McGarey, Barbara (NIH/OD) [E]
> Subject: FW: Advice

> Barb,

b5

> Thanks
> Larry

> From: Koroshetz, Walter (NIH/NINDS) [E]
> Sent: Monday, February 20, 2017 8:14 AM
> To: Tabak, Lawrence (NIH/OD) [E]
> Cc: Schwetz, Tara (NIH/OD) [E]
> Subject: Advice

> Dear Larry,

b5

> Thanks

> Walter

> From: Kurt Fischbeck <fischbeck@ninds.nih.gov<mailto:fischbeck@ninds.nih.gov>>
> Date: Sunday, February 19, 2017 at 5:21 PM
> To: "Koroshetz, Walter (NIH/NINDS) [E]" <koroshetzw@ninds.nih.gov<mailto:koroshetzw@ninds.nih.gov>>, Avi Nath <avindra.nath@nih.gov<mailto:avindra.nath@nih.gov>>
> Subject:

b5

> Dear Walter, Avi:

b5

>
> Thanks!
>
> Kurt
>

b5

>
> <RE: b5

From: Rohrbauh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 6/20/2016 8:39:54 PM
To: Baxevanis, Andy (NIH/NHGRI) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NHGRI/cn=andy]; Carter, Laura (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=carterls]; Chloupek, Larry (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NCI/cn=CHLOUPEL]; Colbert, Melissa (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=colbertmc]; Dearolf, Charles (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=CSR/cn=DEAROLF]; Fonrose, Nadine (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=FonroseN]; Garcia-Perez, Arlyn (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=GarciaA]; Gottesman, Michael (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=GottesmanM]; Joe Kleinman [kleinmanj@mail.nih.gov]; Liu, Paul (NIH/NHGRI) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NHGRI/cn=pliu]; McBurney, Margaret (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=cc/cn=mmcurney]; Milgram, Sharon (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=milgrams]; Owens, Roland (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIDDK/cn=ROLANDO]; Plotz, Paul (NIH/NIAMS) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIAMS/cn=plotzp]; Roberts, Jacqueline (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIDDK/cn=COLLIERJM]; Rohrbauh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Tobias, Geoffrey (NIH/NCI) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NCI/cn=tobiasg]; Walters, Judith (NIH/NINDS) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NINDS/cn=WALTERSJ]; Wanjek, Christopher (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=wanjekc]; Wyatt, Richard G (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=WyattRG]
Subject: FW: NIH rejects petition to override patent on pricey prostate cancer drug

From: Berkson, Laura (NIH/OD) [E]
Sent: Monday, June 20, 2016 4:12 PM
To: Baker, Rebecca (NIH/OD) [E] <bakerrg@od.nih.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Rohrbauh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Culhane, Ned (NIH/OD) [E] <culhanee@mail.nih.gov>; Allen-Gifford, Patrice (NIH/OD) [E] <patrice.allen-gifford@nih.gov>; Higgins, Lauren (NIH/OD) [E] <HigginsL@OD.NIH.GOV>
Subject: NIH rejects petition to override patent on pricey prostate cancer drug

FYI, there is an article in STAT about the Xtandi decision: <https://www.statnews.com/pharmalot/2016/06/20/nih-rejects-patent-petition/>. It links to a pdf of the letter.

NIH rejects petition to override patent on pricey prostate cancer drug



PAUL MORIGI/GETTY IMAGES

NIH Director Dr. Francis Collins

By ED SILVERMAN, *@Pharmabot*
JUNE 20, 2016

After five months of deliberation, the US National Institutes of Health on Monday rejected a request by several consumer groups to override the patent on a prostate cancer drug because the medicine is more expensive in the United States than elsewhere. And one of the consumer groups plans to seek an appeal.

Last January, the groups petitioned the NIH to take this step, which is known as a march-in right, to help US patients because federally funded research was used to create Xtandi. The drug is sold by Astellas Pharma and has an average wholesale price in the United States of more than \$129,000, about two to four times more than what other high-income countries are paying, according to the consumer groups.

Under federal law, a march-in right allows an agency that funds private research to require a drug maker to license its patent to another party in order to “alleviate health and safety needs which are not being reasonably satisfied” or when the benefits of a drug are not available on “reasonable terms.” The drug was developed at the University of California, Los Angeles, with grants from NIH and the US

Department of Defense. The school licensed the drug to Medivation, which struck a marketing deal with Astellas.

However, the NIH denied the petition because there was no information to suggest that Xtandi is or will be in short supply, according to a letter sent on Monday by NIH Director Dr. Francis Collins to Knowledge Ecology International, one of the consumer groups. The agency, which has rarely granted such petitions, noted that the litmus test used in one previous case was whether there were sufficient supplies of the medicine for which a petition was sought.

In a statement, the consumer groups argued the NIH “did not evaluate evidence provided that Astellas charges US residents prices that are far higher than those available to non-US consumers, and that price discrimination against US residents is not consistent with making the product ‘available to the public on reasonable terms,’” as required by federal law.

They also maintained the NIH failed to address evidence that “the unreasonably high price for Xtandi limits patient access, places the drugs on restrictive formularies, causes strain to health care budgets, and requires patients to pay unreasonably high coinsurance and copayments,” all of which justify the use of march-in rights.

They added that the NIH ignored its ability to issue a nonexclusive, royalty-free license to allow Xtandi to be manufactured for use by the federal government. Knowledge Ecology legal and policy counselor Andrew Goldman said there is no precondition about supplies and the NIH is wrong to assert that there is no limit on “excessive pricing” in order to grant a march-in right.

“This is contrary to the legislative intent of the law, and sends a terrible signal about the government’s willingness to confront the high drug prices through available legal mechanisms,” he said.

The consumer group plans to submit an appeal to US Secretary of Health and Human Services Sylvia Burwell and said it will base its appeal on the NIH’s “flawed legal rationale” about the use of march-in rights and “its lack of analysis concerning its refusal to use a royalty-free license.” The group added that it plans to refile this case after a new president takes office next year if the HHS declines its appeal.

As part of its effort, Knowledge Ecology two months ago solicited Biolyse, a small Canadian drug company, to make Xtandi. The drug maker maintained it could supply a version for \$3 per 40-milligram tablet, compared with the \$69.41 that Medicare paid in 2014. Biolyse hoped to be able to supply its version in three years. We left word with a company spokesman and will pass along any reply.

An Astellas spokesman wrote us to say that the company is “pleased that the NIH has concluded that Xtandi is broadly available to patients, and we are committed to continuing our work with our diverse stakeholders to provide patients with affordable access to our medicines.”

The rejection is not a surprise, though.

Two months ago, the Obama administration rejected a request from dozens of congressional Democrats, who call themselves the Affordable Drug Pricing Task Force, to develop guidelines that

would require drug makers to license their patents and put a lid on “price gouging.” They argued the NIH should be more aggressively granting march-in rights in light of the high price of medicine.

At the time, Burwell noted such decisions are made on a case-by-case basis. The NIH previously considered using its march-in authority concerning drug pricing in 2004 and 2013, but determined statutory requirements were not met. Two of those instances involved the Norvir AIDS medicine that was marketed by Abbott Laboratories — now owned by AbbVie — and the Xalatan glaucoma treatment sold by Pfizer.

In response, several lawmakers, including presidential aspirant Bernie Sanders, said they would seek a hearing about NIH use of march-in rights, but that never took place.

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHExchange/CN=OD/CN=ROHRBAUM]
Sent: 2/21/2017 3:12:49 PM
To: Stevens, Ashley J [astevens@bu.edu]
CC: Steve Susalka [b6]
Subject: Re: Thursday

Yes

Sent from my iPhone

On Feb 21, 2017, at 9:53 AM, Stevens, Ashley J <astevens@bu.edu> wrote:

I believe you know I'll be representing AUTM at the KEI Workshop on March-Ins on Friday. I understand that you cannot attend the event.

I will be meeting with various AUTM people to finalize our strategy on Thursday afternoon at 4:00pm at the Georgetown Marriott. Would you be able to attend that meeting?

Best wishes,

Ashley Stevens
Focus IP Group, LLC
Winchester, MA

Office: (781) 721-2670

Cell: [b6]

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 10/24/2016 7:50:47 PM
To: Driscoll, Claire (NIH/NHGRI) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NHGRI/cn=cdriscoll]; Vepa, Sury (NIH/NCATS) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=vepas]
Subject: Fwd: Interview request/chlorcyclizine pricing: BuzzFeed News
Attachments: image001.jpg; image001.jpg

Do you know if

b5

b5

Sent from my iPhone

Begin forwarded message:

From: "Fine, Amanda (NIH/OD) [E]" <amanda.fine@nih.gov>
Date: October 24, 2016 at 8:27:59 PM GMT+1
To: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Cc: "McBurney, Margaret (NIH/OD) [E]" <mmcburney@od.nih.gov>, "Hardesty, Rebecca (NIH/OD) [C]" <rebecca.hardesty@nih.gov>, "Myles, Renate (NIH/OD) [E]" <mylesr@od.nih.gov>, "Wojtowicz, Emma (NIH/OD) [E]" <emma.wojtowicz@nih.gov>
Subject: RE: Interview request/chlorcyclizine pricing: BuzzFeed News

b5

Ideally we'd want a response that is able to answer all of Dan's questions:

What are the institute's priorities when licensing these drugs?
How much progress has this licensee made on marketing this drug?
What were the results of the Phase 1 trial that NIH funded on this drug?
Some observers are asking: why grant an exclusive license to a small, unknown company with no track record of bringing drugs to market?

Thanks Mark! Hope you're not working while on vacation.

Amanda

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, October 24, 2016 3:22 PM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Cc: McBurney, Margaret (NIH/OD) [E] <mmcburney@od.nih.gov>; Hardesty, Rebecca (NIH/OD) [C] <rebecca.hardesty@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: Re: Interview request/chlorcyclizine pricing: BuzzFeed News

I am available.

b5

b5

Sent from my iPhone

REL0000024725

On Oct 24, 2016, at 8:10 PM, Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov> wrote:

Greetings-

I'm including all three of you per Mark's out of office and given that the reporter's deadline is October 28.

NIDDK received the below inquiry from Dan Vergano at BuzzFeed regarding Knowledge Ecology International's (KEI) questions about the drug chlorcyclizine which had/has a small trial at the CC. Attached is a back and forth with NIDDK/NCATS that KEI got through FOIA. Dan's questions are below;

b5

b5

Thank you in advance for your input and guidance,
Amanda

Amanda Fine
Deputy, News Media Branch
National Institutes of Health
Tel: 301-496-7246
Email: amanda.fine@nih.gov
Web: <http://www.nih.gov>

NIH . . . Turning Discovery Into Health

From: Payne, January (NIH/NIDDK) [E]
Sent: Monday, October 24, 2016 2:54 PM
To: OCPLPressTeam <OCPLPressTeam@od.nih.gov>; ODOCPL Interviews (NIH/OD OCPL) <ODOCPLInterviews@mail.nih.gov>
Cc: NIDDK NIDDKMEDIA (NIH/NIDDK) <niddkmedia@niddk.nih.gov>
Subject: Interview request/chlorcyclizine pricing: BuzzFeed News

Hello, NIDDK received an interview request from a BuzzFeed reporter asking about NIH involvement in licensing and drug pricing for chlorcyclizine. Chuck Niebylski, director of NIDDK's Technology Advancement Office, asked that I refer this request to NIH OD as it involves NIH's policy on drug pricing.

Below is the complete email exchange I've had with the reporter, Dan Vergano, and attached is a PDF of an email chain between NIH employees that the reporter received via a public interest group called Knowledge Ecology International, which obtained the records via a FOIA request. (Please note, for background: KEI also published this 2015 post about the same drug.)

REL0000024725

Is NIH OD able to respond to this request?

Thank you,
January W. Payne
Office of Communications and Public Liaison
National Institute of Diabetes and Digestive and Kidney Diseases
NATIONAL INSTITUTES OF HEALTH
Direct 301-435-8115
Cell: b6
Office 301-496-3583
www.niddk.nih.gov

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From: Dan Vergano [<mailto:dan.vergano@buzzfeed.com>]
Sent: Monday, October 24, 2016 12:29 PM
To: Payne, January (NIH/NIDDK) [E] <january.payne@nih.gov>
Subject: Re: BuzzFeed News: press contact / licensing

January,

Thanks for getting back to me

-- The drug is chlorcyclizine (link to license annc't below), and the public interest group, Knowledge Ecology International (which often looks at NIH licenses) is complaining that its request for "reasonable pricing" requirements in the license were brushed aside to the detriment of taxpayers. The group has just received a public records request (a portion is attached) and suggests they show that NIH is worried more about scaring off the licensee than benefiting the taxpayers who funded this drug and have no assurance they won't have to pay excessively high prices for it.

-- I'm looking for an agency response to this contention.

-- My deadline is 10/28/16 at 5 PM EDT

-- My questions would basically be:

How do you respond to their complaint?

What are the institute's priorities when licensing these drugs?

How much progress has this licensee made on marketing this drug?

What were the results of the Phase I trial that NIH funded on this drug?

Some observers are asking: why grant an exclusive license to a small, unknown company with no track record of bringing drugs to market?

I'd have follow-ups depending on the answers, natch, and would want to hear any responses to smarter questions on all this that your folks might have.

Any help appreciated,

Dan Vergano
BuzzFeed News

b6

Dan Vergano | Science Reporter (DC) b6
BuzzFeed
1630 Connecticut Ave. 7th Floor, Washington DC 20009

link: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-06974.pdf>

Dan Vergano | Science Reporter (DC) b6
BuzzFeed
1630 Connecticut Ave. 7th Floor, Washington DC 20009

On Mon, Oct 24, 2016 at 11:57 AM, Payne, January (NIH/NIDDK) [E]
<january.payne@nih.gov> wrote:

Dear Dan,

Thanks for your message. Can you please provide more information so I can look into your request?

- What is the drug name, and can you please briefly describe the issue that has been raised? Also, what is the name of the public interest group?
- What is your hard deadline?
- Can you please provide a few examples of questions you'd like to ask?

Best,

January W. Payne

Office of Communications and Public Liaison
National Institute of Diabetes and Digestive and Kidney Diseases

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REL0000024725

From: Dan Vergano [mailto:dan.vergano@buzzfeed.com]
Sent: Monday, October 24, 2016 11:25 AM
To: NIDDK NIDDKMEDIA (NIH/NIDDK) <niddkmedia@niddk.nih.gov>
Subject: Fwd: BuzzFeed News: press contact / licensing

Krysten's email responder suggested I send this note to this contact. I have also left a phone message with the press office. I am looking for comment this week.

Ms. Carrera,

I'm a science reporter at BuzzFeed News. I'm looking for a press contact at NIDDK who can address a drug licensing issue at your institute. A public interest group is raising questions about one of your licenses and I'd like to get a response from the institute.

Thanks for any help,

Dan Vergano

BuzzFeed News

b6

Dan Vergano | Science Reporter (DC) | **b6**
BuzzFeed
1630 Connecticut Ave. 7th Floor, Washington DC 20009

JANUARY PAYNE

Senders Cc

REL0000024725

@ National Institutes of Health

National Institutes of Health | 9000 Rockville Pike, Bethesda, MD 20892, USA | Official website of the National Institutes of (NIH). NIH is one of the world's foremost medical research centers. An agency of...



January Payne on LinkedIn



@NIH | 663K followers | 6K tweets - 3 hours ago

There's still time to submit your @NIH_LRP application! Get started on yours today. Deadline is Nov.15 bit.ly/2e7QDzt #studentdebt



Search for January Payne on Google

Dan is using Senders. [View / edit your own Card](#)

<Reasonable Pricing - Virotas NIH .pdf>

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHExchange/CN=OD/CN=ROHRBAUM]
Sent: 2/21/2017 8:48:46 PM
To: Myles, Renate (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=recipients/cn=mylesr]
Subject: Fwd: Crispr in the public domain

Could [b5]?

Sent from my iPhone

Begin forwarded message:

From: "Molteni, Megan" <Megan_Molteni@wired.com>
Date: February 21, 2017 at 3:42:23 PM EST
To: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Cc: "Myles, Renate (NIH/OD) [E]" <mylesr@od.nih.gov>
Subject: Re: Crispr in the public domain

Understood. Thank you for getting back to me. I'm planning to use the WARF case to describe possible precedence and I know you worked closely on that, so let me know if you have any thoughts regarding its relevance as an analog.

Best,
M

From: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Date: Tuesday, February 21, 2017 at 12:35 PM
To: Megan Molteni <Megan_Molteni@wired.com>
Cc: "Myles, Renate (NIH/OD) [E]" <mylesr@od.nih.gov>
Subject: Re: Crispr in the public domain

I am not able to comment on a legal matter that may come before the agency

Sent from my iPhone

On Feb 21, 2017, at 3:17 PM, Molteni, Megan <Megan_Molteni@wired.com> wrote:

Hi Mark,

I'm a science reporter with WIRED. Today I'm working on a story to follow up on last week's Crispr/Cas9 patent ruling—specifically, whether or not the broadness of the existing patent claims and the narrowness of their exclusive licensing agreements might motivate the NIH to exercise its discretion to mandate Crispr nonexclusively to the public domain. Knowledge Ecology International is planning to file a petition for such federal action this week. And I'd be very interested to hear your thoughts on the matter. Give me a call, or shoot me an email if you are free to comment.

Thanks, and all best,
Megan Molteni
Staff Writer | WIRED
o: 415.276.4924

REL0000024726

c: 920.242.4952
@MeganMolteni

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/OD/CN=ROHRBAUM]
Sent: 2/24/2017 7:33:00 PM
To: Mowatt, Michael (NIH/NIAID) [E] [/O=NIH/OU=NIH/OD/CN=NIAID/cn=MMOWATT]
Subject: Fwd: KEI

Sent from my iPhone

Begin forwarded message:

From: "Deutch, Alan (NIH/NHLBI) [E]" <deutch@nhlbi.nih.gov>
Date: February 24, 2017 at 1:57:45 PM EST
To: "Reichman, Uri (NIH/NHLBI) [E]" <uri.reichman@nih.gov>, "Shmilovich, Michael (NIH/NHLBI) [E]" <michael.shmilovich@nih.gov>, "Thalhammer-Reyero, Cristina (NIH/NHLBI) [E]" <cristina.thalhammer-reyero@nih.gov>
Cc: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Subject: KEI

After some nonprofit organizations made noise about the U.S. Army's plans to license a Zika vaccine to Sanofi, several lawmakers are chiming in to say it's a bad idea.

Eleven congressional Democrats wrote to Acting Secretary of the Army Robert Speer to "strongly urge" against the move, first announced in a Federal Register post in December.

Among the first to oppose that plan was Knowledge Ecology International (KEI), a nonprofit that argued the license wouldn't be necessary to motivate Sanofi to develop the shot through to the market. Further, the group is concerned about future pricing of a vaccine that was developed with public funds.

RELATED: U.S. Army's planned Zika vaccine license to Sanofi raises nonprofit's ire SEE BELOW

Worldwide charity Médecins Sans Frontières came out against the plan last month with arguments that the license could be a barrier to access.

Now, members of the House, including frequent pharma critic Rep. Elijah Cummings, write that the license as planned doesn't have enough pricing and access safeguards. They too say it was developed with public funds, and "implore" the Army to "instead issue a limited license" with more restrictions.

If the plan does go through, the lawmakers would like to see the license enable the federal government to intervene if Sanofi priced it out of reach to "millions of Americans" who might need a shot "they paid to develop."

On Thursday, a Sanofi spokesperson agreed that "anything that curtails innovation in healthcare R&D would not be best for the public good." As the world's top flavivirus vaccine developer, Sanofi is "well-positioned" to work with the Army's candidate, she said, and "is capable of making it available to those areas that need it most."

Sanofi partnered with the U.S. Army on the technology—dubbed Zika purified inactivated virus (ZPIV)—back in July and later won a \$43 million grant from the government to support the work. The company could ask for further financial support "if all goes well," a spokesperson previously told FiercePharma.

Responding to KEI's initial concerns, a Sanofi spokesperson said the drugmaker is "sharing inherent risks" in developing the vaccine. The company has "modeled various scenarios" for the virus and its prevalence, and the vaccine's profitability will depend on the "nature of the epidemiology and spread of the virus."

REL0000024728

Experts have predicted a Zika vaccine could be an opportunity worth \$1 billion or more, because travelers could pay a high price for protection.

The U.S. Army's decision to transfer a Zika vaccine candidate's license to development partner Sanofi has prompted protest from a nonprofit worried about the legality of the plan and the product's future pricing.

Developed by Army scientists, the Zika purified inactivated virus vaccine is currently in phase 1 testing at the Walter Reed Army Institute of Research and the National Institutes of Health. Under a development agreement with Sanofi, the pharma is to prep for larger-scale development and manufacturing.

But Knowledge Ecology International has some concerns about the Army's plan to transfer the vaccine license to the company. It's worried, for one, "about how the price of the vaccine may affect access." The Army disclosed its plan Dec. 9 in a Federal Register post.

Additionally, KEI believes the license would "not be legal" because it isn't necessary to motivate the pharma company to develop the vaccine through to the market; so far, the candidate has been supported by "extensive government subsidies," KEI argues.

If the vaccine were to earn approval, Sanofi would win a priority review voucher from the FDA, KEI says. Those vouchers have been growing in value in recent years. One sold for \$350 million in August 2015. According to a draft KEI statement, that is a "valuable incentive in itself."

A Sanofi spokesperson said the company is "sharing inherent risks" by partnering with the government on Zika, adding that, even with tax-funded support, the drug giant is "still assuming financial and opportunity risks by devoting human and other resources to this project that otherwise would be working on other projects."

"We have been informed of the objections and welcome the opportunity to respond," according to the spokesperson.

Sanofi says it has "modeled various scenarios" for the virus and its prevalence, adding that the "nature of the epidemiology and spread of the virus will impact the degree of profitability." Sanofi said it's "way too early" to talk about pricing or when the vaccine candidate might be available.

In seeking to learn more about the plan, KEI requested information about the vaccine's related intellectual property, the licensing agreement and the amount of government funding the project has received. The Army declined, KEI says, and the nonprofit is objecting to the "lack of transparency" in the process. After hearing from KEI, the Army extended the comment period about its plan to Jan. 23, a KEI representative said.

Sanofi partnered with the U.S. Army on the technology in July 2016 and later won a \$43 million government grant to support the work. That money covers development through phase 2, and Sanofi said it might ask for phase 3 or other support "if all goes well" with the program. With many service members deployed in endemic areas, work on the vaccine is part of the Army's response to Zika.

The tie-up is one of several inked by government agencies in response to the Zika outbreak. Shortly after Sanofi signed on with the Army, GlaxoSmithKline partnered with the NIH to tackle Zika with technology called self-amplifying mRNA, or SAM. Takeda later entered the vaccine hunt with a \$312 million deal with the U.S. government's Biomedical Advanced Research and Development Authority (BARDA).

An R&D path spanning government and industry is not uncommon, as many top drugs start out in tax-funded labs and eventually make their way to biopharma companies for further development.

Industry-watchers have said a Zika vaccine could be a lucrative prospect even outside countries where the disease is endemic, thanks to international travelers' ability to pay a high price for protection. In addition, campaigns in endemic areas might target girls to protect against the virus and its associated birth defects.

The Army didn't immediately respond to a request for comment.

According to its website, the nonprofit KEI "searches for better outcomes, including new solutions, to the management of knowledge resources."

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 12/20/2016 1:12:34 PM
To: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: Re: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits
Attachments: image001.jpg; image002.jpg; image003.jpg; image004.jpg; image005.jpg; image006.jpg; image007.jpg

I talked to them several times with Renata, the focus was on intramural. I believe March in came up and I said the govt and many others have never interpreted it as price control but it was not a major part of the conversation. They mostly wanted to know how NIH made these deals, how does the money flow, and why did this company get such a valuable set of IP, which we explained is Monday morning quarterbacking because initially there was not much interest or competition for the licenses.

Sent from my iPhone

On Dec 20, 2016, at 7:28 AM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:

This is exactly the reason why I recommended that

b5

b5

From: Joe Allen [<mailto:jallen@allen-assoc.com>]
Sent: Monday, December 19, 2016 9:39 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Robert Hardy <rhardy@cogr.edu>;
Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: Re: Fwd: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

That's the second NYT's article in two weeks pushing the same theme. Did you mention that Bayh-Dole doesn't sanction marching in to control prices of products on the market? That point is completely missing. They "prove" their argument by quoting all the usual suspects. This feels like a campaign that's been in the works for a while and was designed to pressure the anticipated Clinton Admn while it was forming. Looks like they decided to go ahead to see if they can move the Trump people. Trump mentioned on Friday his interest in controlling drug costs, so they may hope he'll see march in rights as a useful tool. Looks like we'll have our work cut out for us again next year to refight this battle.

Interestingly, Jamie Love emailed me this afternoon saying that his conference on compulsory licensing is moved to Feb. 24. Without committing myself to participate, I'll see if I can find out the structure and who's speaking (although this article is probably a good road map).

Onward and upward...

On 12/19/2016 8:57 PM, Rohrbaugh, Mark (NIH/OD) [E] wrote:

Sent from

Health

REL0000024730

Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

By MATT RICHTEL and ANDREW POLLACK DEC. 19, 2016

Dr. Steven Rosenberg, left, who has led the surgery branch at the National Cancer Institute for 42 years, and Dr. Arie Belldegrun, the founder of Kite Pharma. Credit Jesse Dittmar (left) and Emily Berl (right) for The New York Times

Enthusiasm for cancer immunotherapy is soaring, and so is Arie Belldegrun's fortune.

Dr. Belldegrun, a physician, co-founded Kite Pharma, a company that could be the first to market next year with a highly anticipated new immunotherapy treatment. But even without a product, Dr. Belldegrun has struck gold.

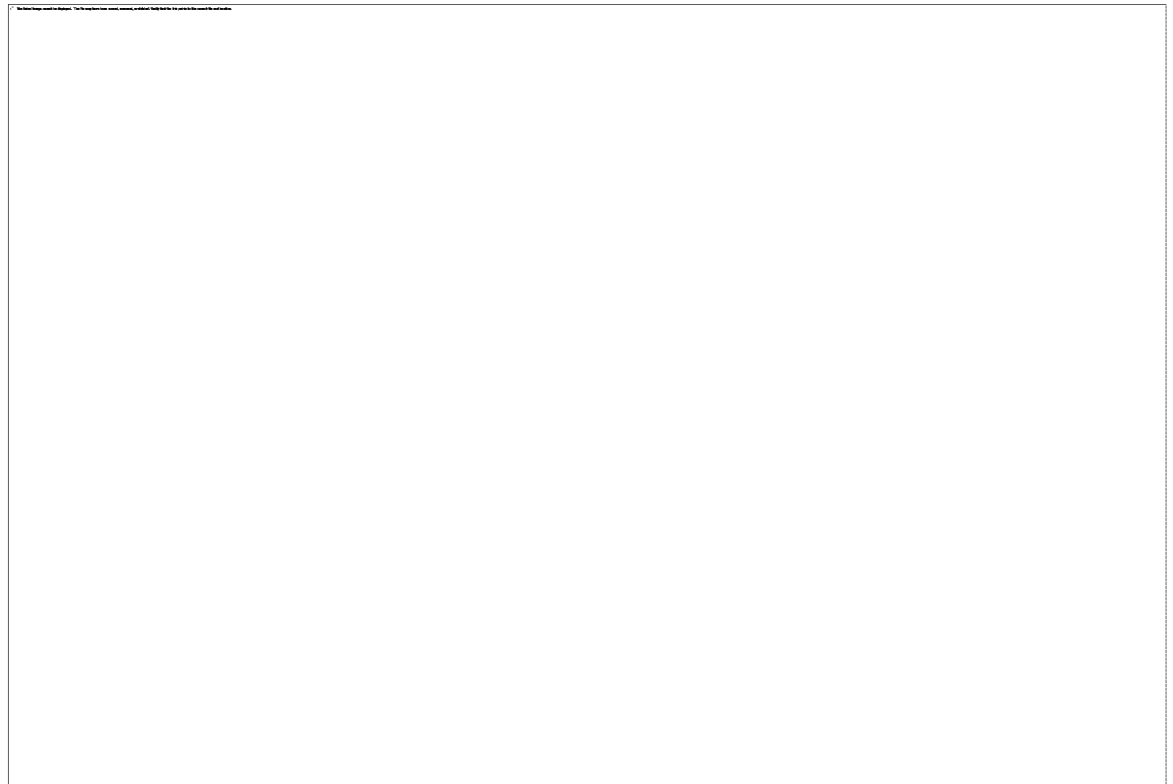
His stock in Kite is worth about \$170 million. Investors have profited along with him, as the company's share price has soared to about \$50 from an initial price of \$17 in 2014.

The results reflect widespread excitement over immunotherapy, which harnesses the body's immune system to attack cancer and has rescued some patients from near-certain death. But they also speak volumes about the value of Kite's main scientific partner: the United States government.

Kite's treatment, a form of immunotherapy called CAR-T, was initially developed by a team of researchers at the National Cancer

Institute, led by a longtime friend and mentor of Dr. Belldgrun. Now Kite pays several million a year to the government to support continuing research dedicated to the company's efforts. The relationship puts American taxpayers squarely in the middle of one of the hottest new drug markets. It also raises a question: Are taxpayers getting a good deal? Defenders say that the partnership will likely bring a lifesaving treatment to patients, something the government cannot really do by itself, and that that is what matters most. Critics say that taxpayers will end up paying twice for the same drug — once to support its development and a second time to buy it — while the company reaps the financial benefit. "If this was not a government-funded cancer treatment — if it was for a new solar technology, for example — it would be scandalous to think that some private investors are reaping massive profits off a taxpayer-funded invention," said James Love, director of Knowledge Ecology International, an advocacy group concerned with access to medicines.

Photo



Dr. Rosenberg and Dr. Belldgrun in the mid-1980s. Dr. Belldgrun became a research fellow for Dr. Rosenberg at the cancer institute in 1985. Credit Kite Pharma
The debate goes squarely to one of the nation's most vexing challenges: rising health care and drug prices. Kite is one of a growing number of drug and biotech companies relying on federal laboratories. Analysts expect the company to charge at least \$200,000 for the new treatment, which is intended as a one-time therapy for patients.

While the law allows the government to demand drug-price concessions from its private-sector partners, the government has declined to do so with Kite and generally disdains the practice. Insisting on lower prices, federal researchers say, would drive away innovative partners that speed the drug-development process and benefit patients. But with the government doing so much pivotal research, others say that the private sector cannot afford to walk away.

“The market is so reliant on the knowledge and know-how that comes out of the government and academic labs,” said Dr. Aaron Kesselheim, director of the Program on Regulation, Therapeutics and Law at Brigham & Women’s Hospital in Boston.

Price curbs, he said, “would not suddenly lead to a total abandonment of this pipeline. It couldn’t possibly.”

Drug makers would be especially unlikely to turn away from immunotherapy, where the promising science has set off a “gold rush mentality,” according to Mark Edwards of Bioscience Advisors, a company which tracks pharmaceutical licensing deals. The National Institutes of Health, the parent agency of the National Cancer Institute, currently has about 400 cooperative research agreements with companies, and licenses hundreds of patented inventions for private-sector development.

Kite executives and national health officials characterize their partnership as a model arrangement in a system established by Congress three decades ago. The system has given birth to the cancer drug Taxol, the AIDS drug Prezista, two cervical cancer vaccines and a widely used test for H.I.V. infection, among other innovations.

Continue reading the main story

Photo

Dr. Rosenberg in his lab at the cancer institute in Bethesda, Md. Partnerships between government labs and drug companies are “absolutely essential or many discoveries will not see the light of day,” he said. Credit Jesse Dittmar for The New York Times

Kite’s first drug, called KTE-C19, could help thousands of patients each year in the United States with certain blood cancers. If it succeeds, it could generate sales of \$1 billion to \$2 billion annually, according to Wall Street analysts, making it among the most lucrative drugs to come from government research. But the government’s share of any Kite success would be modest, much lower than some academic research groups have wrangled in immunotherapy deals worth hundreds of millions of dollars. Federal officials counter that the reward to the taxpayer is not money but the drug itself.

“This is exactly the way things should work,” said Dr. Steven Rosenberg, who has led the surgery branch at the National Cancer Institute for 42 years and led development of Kite’s drug. Such partnerships, he said, are “absolutely essential or many discoveries will not see the light of day.”

Moreover, government officials say, companies in such deals must take significant financial risks and expenditures on their own, without any guarantee that the drug will be approved. Kite says it has spent more than \$200 million on research and development, including running larger clinical trials than those conducted by the cancer institute, and recently spent about \$30 million to build a factory that will be able to make treatments for up to 5,000 patients a year.

Setting the price of the drug, Dr. Rosenberg said, “is for the marketplace.”

A Public-Private Partnership

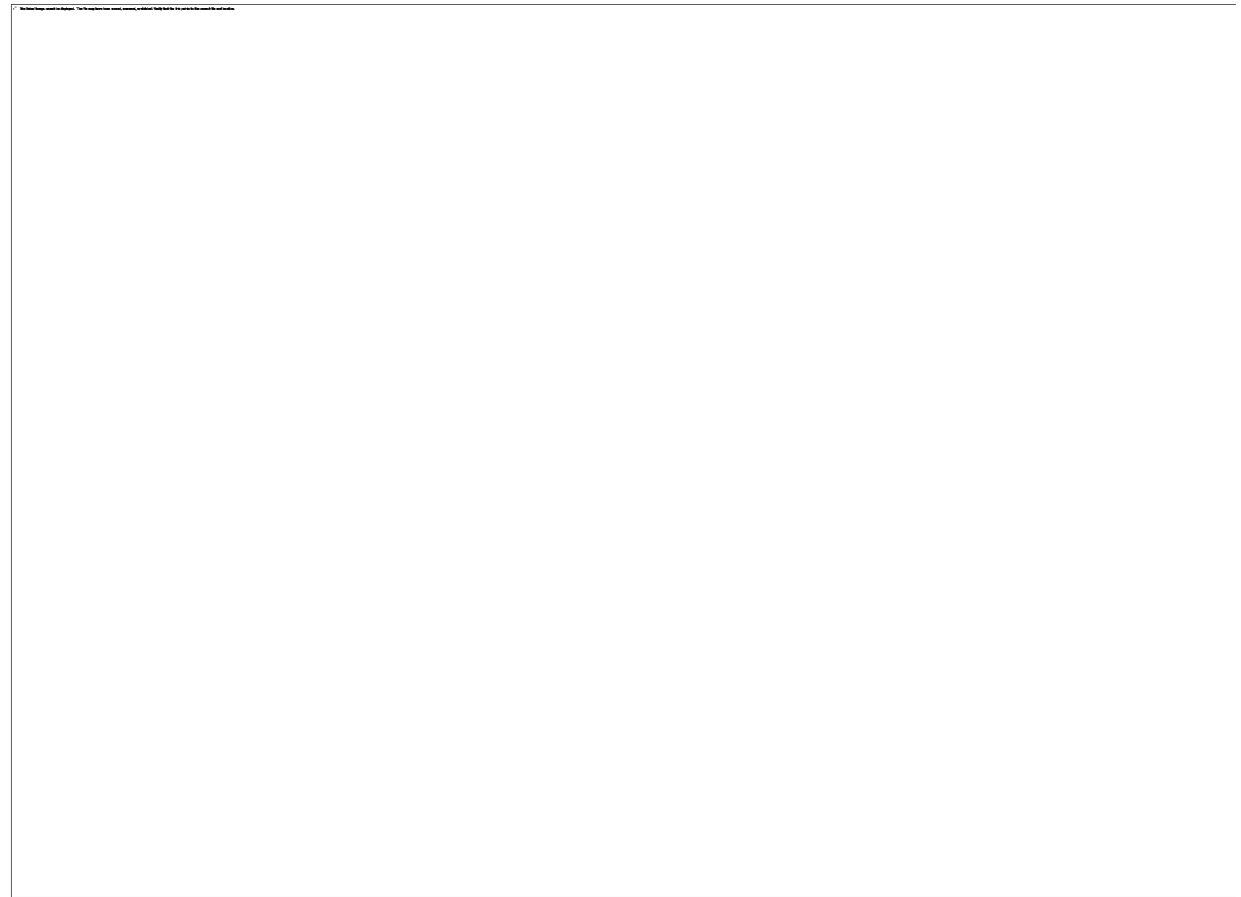
Like many business deals, this one began with a personal relationship — in this case between Dr. Rosenberg and Dr. Belldgrun.

After finishing medical school in his native Israel, performing surgery in helicopters for the Israeli armed forces, and completing residency at Brigham & Women’s Hospital, Dr. Belldgrun became a research fellow for Dr. Rosenberg at the N.C.I. It was 1985, and Dr. Belldgrun was put to work on a new project of Dr. Rosenberg’s — extracting tumor-fighting immune cells from cancer patients, multiplying them in the laboratory, and putting them back in.

“He was one of the more outstanding fellows to come through,” said Dr. Rosenberg, 76, who is widely considered a cancer research luminary.

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Photo



Dr. Belldgrun, center, at the Nasdaq stock exchange, where Kite Pharma is listed. The company was founded in 2009 and went public in 2014. Credit Nasdaq, 2016

When the fellowship ended in 1988, Dr. Belldgrun became a prominent surgeon at the University of California, Los Angeles, but the two men stayed in touch. Eventually, Dr. Belldgrun, 67, got the entrepreneurial bug. He co-founded a biotech company, Agensys, which was acquired by a bigger company for more than

\$500 million. He was also involved with Cougar Biotechnology, which developed the prostate cancer drug Zytiga and was acquired by Johnson & Johnson for \$1 billion in May 2009. A month later, Dr. Belldgrun formed Kite with a group of colleagues and investors to pursue cancer immunotherapy.

That same month, a Florida marine contractor named Eric Karlson, whose non-Hodgkin's lymphoma was advancing despite four prior treatments, became the first patient treated by Dr. Rosenberg with what would eventually become KTE-C19. The treatment entailed removing some of Mr. Karlson's immune system T cells from his blood, genetically engineering them to recognize and fight his cancer, multiplying the T cells to huge numbers in the laboratory and transferring them back into his body. After two such treatments, Mr. Karlson remains alive and cancer-free eight years later.

Kite initially thought it would pursue an approach to immunotherapy known as cancer vaccines, but in 2010, Dr. Belldgrun visited Dr. Rosenberg and was shown the X-rays of Mr. Karlson and of a second patient.

Dr. Belldgrun was bowled over. "I had no doubt that this is going to be a drug and, more than that, it will become a platform for multiple products," he recalled. "We never looked back."

Over the next two years, the National Cancer Institute worked out a deal with Kite that was signed in 2012. It was the first of eight contracts between the government and the company that generally take two forms.

In one type of contract, Kite licenses patented inventions and agrees to pay the government royalties, roughly 5 percent of sales of any commercial product arising from a particular patent.

However, there is no such license specifically for KTE-C19 because the underlying treatment was not patented by the N.C.I., so royalties will be minimal.

Officials say the agency did not apply for a patent because the treatment was similar to what others had been developing. Also, at the time the treatment was first created, in 2007, immunotherapy was considered to have dim commercial prospects.

"Back then, we didn't even think about commercial aspects," said Dr. James N. Kochenderfer, a scientist at the agency who designed the treatment when working in Dr. Rosenberg's group.

Under the second type of contract, known as a cooperative research and development agreement, Kite provides money to the N.C.I. to support research. Kite is now paying \$3 million a year to Dr. Rosenberg's lab and has provided \$7.5 million to it in total since 2012. Based on its regulatory filings, Kite is paying \$7.8 million a year for research agreements and licenses in total, with at least \$4 million of that going to the cancer institute and the rest to academic or corporate partners.

The taxpayer has invested, too. Dr. Rosenberg estimated that the government has spent roughly \$10 million over the years on what has become KTE-C19. He said Kite's \$3 million a year is about

equal to the taxpayer funding in that area and has helped speed research.

These days, researchers from Kite and the cancer institute, typically including Dr. Rosenberg and Dr. Belldgrun, confer by conference call every other Thursday for 90 minutes. Kite employees have spent long periods at the N.C.I., learning how to manufacture the therapy and how to treat patients in advance with chemotherapy.

“We shouldn’t underestimate the value and the importance of N.I.H., not only to Kite but to the whole field of engineered T-cell therapy,” Dr. Belldgrun said. When Kite signed its first deal with the cancer agency, he said, it “tapped into six years of monumental work that they had done.”

Some immunotherapy competitors marvel at the company’s coup in tapping into the agency’s expertise. “They got 20 years of research all together in one scoop,” said Dr. Carlos Paya, chief executive of Immune Design, which is pursuing a different approach.

But government officials say few, if any, other companies were interested in the technology at the time Dr. Belldgrun came calling. Dr. Rosenberg said that before Kite, a few companies, including Johnson & Johnson, had looked at an earlier version of his technology but were wary because treatment involved processing each patient’s cells.

Government-developed technology available to be licensed to companies is posted on the website of the National Institutes of Health. And when the agency intends to grant a license to a particular company, it publishes that in the Federal Register, inviting public comment and possible competing offers. Both steps were taken in the case of Kite, officials said.

Kite did not get everything the cancer institute has developed in the field. Some other companies, including Opus Bio and Bluebird Bio, got rights to some products, in part because the companies had special expertise that the agency’s researchers desired. But Kite seems to have gotten the balance of them and N.C.I. technology accounts for the majority of its pipeline of possible products, though the company is diversifying.

Photo

A slide that Kite Pharma used in presentations to potential investors pointed out the company's relationship with Dr. Rosenberg.

Dr. Rosenberg professes no interest in the business side of the Kite relationship. He does not own stock in any company, even Kite, though he could get up to \$150,000 a year in patent royalties if some of Kite's efforts pay off.

Dr. Belldegrun, in contrast to his mentor, has commercial flair. He is known for his sharp business suits, lives in the Bel-Air neighborhood of Los Angeles, and seems as comfortable on Wall Street or in high society as in the operating room.

Kite's relationship with the N.C.I. is an important part of its appeal to investors. In some presentations, Dr. Belldegrun has shown a photograph of himself with Dr. Rosenberg in their younger days. And he persuaded Dr. Rosenberg to speak at Kite's first big meeting for investors in June 2015, the only time he has ever spoken to Wall Street.

In emails obtained through a Freedom of Information Act request by Knowledge Ecology International, Dr. Belldegrun praised Dr. Rosenberg's talk and sent him copies of investment reports from the conference written by Wall Street analysts.

"Thank you for making the effort to come to NY," Dr. Belldegrun wrote. "I heard only raving reviews about your presence and presentation."

A 'Reasonable' Question

The reliance of private companies on government-funded research goes well beyond obvious cases like Kite. In many instances, companies work with universities or medical centers that, in turn, have been funded from the \$32 billion annual budget of the National Institutes of Health.

Kite's two main competitors, Novartis and Juno Therapeutics, for instance, derived similar immunotherapy treatments largely from academic institutions, developed at least in part with government funding. Novartis has a relationship with the University of Pennsylvania, and Juno with the Memorial Sloan Kettering Cancer Center, the Fred Hutchinson Cancer Research Center and Seattle Children's Hospital.

"For the most important drugs you'll see some public-sector involvement," said Bhaven Sampat, an associate professor of health policy and management at Columbia University. He was one author of a study that found that 9 percent of all drugs approved between 1988 and 2005 were based directly on a patent held by the public sector. But 47.8 percent of the drugs relied at least indirectly on some federally funded research.

Continue reading the main story

Photo

Eric Karlson at his home on Marco Island, Fla., this month. Mr. Karlson's non-Hodgkin's lymphoma was successfully treated by Dr. Rosenberg with what would eventually become KTE-C19.
Credit Scott McIntyre for The New York Times

The figures were higher for more medically important drugs: 17.4 percent had a direct public-sector patent, while 64.5 percent had at least an indirect public-sector influence.

These figures are up sharply from before the 1980s. Such partnerships and licensing deals were encouraged by the 1980 Bayh-Dole and Stevenson-Wydler Acts, and the 1986 Federal Technology Transfer Act. The laws are credited with jump-starting the biotechnology industry.

But from the beginning, some people questioned whether taxpayers were getting a bad deal.

Perhaps the best-known drug developed from a cooperative research and development agreement — the cancer drug Taxol — was the subject of several congressional hearings in the early 1990s that investigated whether the drug's maker, Bristol-Myers Squibb, charged too much and whether the government recouped enough of its investment. In the end, the pricing was left unchanged.

The N.I.H. argues that if it imposes pricing restrictions, it won't get partners. In fact, in 1995, it struck from its negotiating tactics a goal that prices be "reasonable."

"Companies will not take technologies from us if we say the government will decide in the future what the price will be," said Mark Rohrbaugh, who ran the technology transfer office at the institutes from 2001 to 2013 and is now an adviser to the agency. After the "reasonable price" clause was struck, he said, there was a threefold increase in partnership deals.

The N.I.H. can collect royalties from successful products to help offset the costs of the research, but so far these royalties have been small, amounting to an estimated \$135 million in the last fiscal year from 870 licenses, with the bulk of the money coming from a small number of drugs.

"We're not preoccupied with financial value," Dr. Rohrbaugh said. "Our mission is treatment of people and improving public health."

In that regard, the government's bet on a small company like Kite, which might have seemed risky, appears to be paying off so far.

Dr. Belldegrun has largely delivered on promises to raise money, assemble an experienced staff, build the factory, conduct clinical trials and begin to apply for regulatory approval. Once considered the underdog to Novartis and Juno, Kite might be the first reach the market.

Photo

Scans of Mr. Karlson's body before and after his treatment. In the cross-sections on the left, the arrows point to signs of lymphoma in areas such as his armpits, chest, spleen and pelvis. Credit National Cancer Institute

Academic centers and companies often drive harder bargains in licensing technology. In some cases, academic centers own a stake in a company they license technology to, allowing them to reap a financial windfall if the company does well. Both the Hutchinson cancer center and Sloan Kettering have owned stock in Juno and are entitled to substantial payments — up to \$350 million and \$150 million — if Juno's stock reaches certain levels.

The N.I.H. does not take equity positions in companies to avoid an appearance of a conflict of interest. So to critics of the government deals, drug prices are crucial to understanding taxpayer value. After all, they ask, is a drug truly widely available — which is what the government says is its measure of success — if it costs too much for some people?

Rachel Sachs, an associate law professor at Washington University in St. Louis and expert in innovation policy, said the government had every right to seek price concessions. She noted that the government, through Medicare and Medicaid, was effectively buying its inventions back from itself. "The public is paying for the research and to the extent that many people, if not most, will pay through public insurance, we're paying again," she said.

Hillary Clinton, in her campaign for president, promised to set new rules for federal support of research so that Americans “get the value they deserve” for the money taxpayers spend in supporting research. It is not clear how President-elect Donald J. Trump will approach these issues; he has said he favors reducing health care costs, but Republicans, who control Congress, too, have opposed government involvement in price setting.

One mechanism to control pricing already exists. It is called march-in rights, and it lets the N.I.H. take back control of a patent on an invention made with federal funding if the drug is not being made available to the public on reasonable terms. The tool has gone unused.

Earlier this year, Knowledge Ecology International and another advocacy group, the Union for Affordable Cancer Treatment, petitioned the agency to exercise march-in rights on Xtandi, a prostate cancer drug that was developed by federally funded researchers at U.C.L.A. It said the price in the United States of about \$129,000 a year, two to four times that in other developed countries, meant the drug was not reasonably available. The effort was supported by other public interest groups and some Democratic members of Congress.

U.C.L.A. made more than \$500 million by selling its royalty rights to the drug. But the N.I.H. declined to exercise its march-in rights on Xtandi, arguing that it was not qualified to judge whether a drug’s price is reasonable and that a high price does not mean a drug is not being made available to the public.

“N.I.H. has made it clear that its job is not to decide prices of drugs, period,” Dr. Rohrbaugh said

Kite says it has not decided what to charge for KTE-C19, but Dr. Belldegrun hinted that Kite’s therapy might be relatively expensive because ideally it would be a single treatment that would cure the patient, not a drug that would have to be taken continuously. He added that Kite would take steps to make sure that everyone who needed the drug could get it.

Meantime, the relationship between Kite and the National Cancer Institute is expanding to develop treatments for other cancers, including one technique Dr. Rosenberg thinks could be used to attack solid tumors like colon, breast and lung cancer.

“The potential for broad applicability is huge,” he said.

That could mean many lives saved and maybe more billion-dollar drugs for Kite and its investors, with the American taxpayer right in the middle of the deal.

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From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 2/23/2017 10:16:43 PM
To: David Winwood [David.Winwood@pbrc.edu]
CC: Joe Allen [jallen@allen-assoc.com]; Michael Waring [mwaring@umich.edu]; Susalka, Stephen [SSusalka@autm.net]; Stevens, Ashley J [astevens@bu.edu]; astevens@fipgllc.com; Smith Barnes, Leef [lsmithbarnes@autm.net]; Fred Reinhart [fred@research.umass.edu]; Mary Albertson [mary.albertson@stanford.edu]
Subject: Re: KEI Preparation

Article on CRSPR by Jon Cohen in tomorrow's Science edition, basically saying despite UC's bluster, the Broad patent will dominate use in eukaryotes.

"The most lucrative future of CRISPR, Cook-Deegan stresses, lies not in the patents on it but in the medicines, crops, and other products scientists use the genome editor to create. "Big revenues are likely to be beyond the horizon of the current patent portfolio, so the value of current patents is being exaggerated," he says. 'The real value will come from getting products to market as quickly as possible so [companies] can get whatever revenues might be had.'"

Sent from my iPhone

On Feb 23, 2017, at 4:03 PM, David Winwood <David.Winwood@pbrc.edu> wrote:

Just opening line.

Sent from my iPhone

On Feb 23, 2017, at 4:01 PM, Joe Allen <jallen@allen-assoc.com> wrote:

me too

On 2/23/2017 3:59 PM, Michael Waring wrote:

just dialed in and on hold..

M

On Thu, Feb 23, 2017 at 3:53 PM, Susalka, Stephen
<SSusalka@autm.net> wrote:

Dear All,

For those of you calling into this meeting - please call b6
b6 (Code b6). Talk to you soon.

Sincerely,
Steve

Stephen J. Susalka, Ph.D., CLP
Executive Director
Association of University Technology Managers (AUTM)
Advancing Discoveries for a Better World

b6

Ssusalka@autm.net

On Feb 23, 2017, at 9:52 AM, Joe Allen <jallen@allen-
assoc.com> wrote:

Excellent, one suggestion-- on p. 8, iii, modify to
read:

*Some of the language in the legislative history that
was cited in the Norvir petition in support of
March-in rights...*

In their paper (which launched this whole mess)
Arno and Davis cite legislative history supporting
marching in to control prices. However, with the
exception of their misquote you cite above, none of
it relates Bayh-Dole but occurred in other hearings
(which means that it isn't legislative history of
Bayh-Dole). Limiting your remark to the Norvir
petition makes it much harder for them to throw
extraneous legislative history at you in rebuttal of
your point.

On 2/23/2017 7:43 AM, Stevens, Ashley J wrote:

See addition of conclusory section
at the end.

See you at 4:00pm.

Best wishes,

Ashley Stevens

Focus IP Group, LLC

Winchester, MA

Office: (781) 721-2670

Cell:

b6

REL0000024733

From: Susalka, Stephen
[mailto:SSusalka@autm.net]
Sent: Friday, February 17, 2017
5:24 PM
To: Stevens, Ashley J
<astevens@bu.edu>;
astevens@fipgllc.com
Cc: Joe Allen <jallen@allen-
assoc.com>; Smith Barnes, Leef
<lsmithbarnes@autm.net>; Michael
Waring <mwaring@umich.edu>;
Dave Winwood
<David.Winwood@pbrc.edu>; Fred
Reinhart
<fred@research.umass.edu>; Mary
Albertson
<mary.albertson@stanford.edu>
Subject: KEI Preparation

Dear Ashley,

On behalf of AUTM, I want to thank you for speaking on behalf of AUTM at the KEI Forum next Friday April 24th. Dave (CCed along with my other colleagues) will be authorizing you to speak on behalf of AUTM for this event. For everyone's convenience, the agenda for the KEI forum is at the bottom of this email.

Although you are well informed about the Bayh-Dole Act and its positive impact on technology transfer, and are aware of KEI's relentless push to use the March-in provisions as a way to control drug pricing and perhaps even prevent Universities from asserting ownership of federally funded IP generated, we wanted to have a prep session on Thursday

February 23rd at 4pm (TBD – but likely to be in the Marriott Georgetown). Dave, Fred, Leef, Mike, and I will be there, and Joe Allen will be joining us by phone (if not in person).

I wanted to use this one email to summarize a lot of content that might be helpful during your presentation:

1. AUTM's general talking points on compliance (attached)
2. **Confidential** Third Party Internal Talking Points on **b4** (attached - please do not forward them)
3. 2 emails from Joe Allen on the topic (see below)

Please let me know if you need any additional information and we will see you on

Thursday. My cell is **b6**
b6 please pass on yours.

EMAIL #1:

As Trump talks 'America First' on trade, pharma presses its global patent rights

by Eric Sagonowsky |

In new recommendations to the U.S. Trade Representative, pharma's trade group cited weak patent laws in more than a dozen countries. As the Trump Administration formulates its "America First" plans for trade deals around the world, the pharma industry is pressing U.S. officials to focus on its patent-law and enforcement worries in more than a dozen countries.

The industry group PhRMA, in new comments to the U.S. Trade Representative, critiques patent regimes it considers problematic, with a recent dustup in Colombia making an appearance. The comments come as the USTR is formulating its annual report on IP regulations, which red-flags countries whose oversight officials consider sub-par.

Last year, Colombian officials forced a price cut for Novartis' cancer med Glivec, after threatening to force the company to allow generics makers to produce cheap copies. PhRMA is [recommending](#) (PDF) Colombia be included on the USTR's Priority Watch List. The industry group said Colombia has "weak patent enforcement," "increased regulatory barriers" and "arbitrary and non-transparent market access policies," among other concerns.

Along with Colombia, countries including Canada, China and India made PhRMA's list for inclusion in the Priority Watch List. PhRMA submitted its comments as part of an annual review for the USTR's Special 301 report, which is to be published in April.

International trade deals—which typically include agreements on IP protections—are something Pfizer CEO Ian Read touched on during his company’s fourth-quarter earnings call. He said that he agrees with new U.S. President Donald Trump that, when it comes to “free riding on American innovation of pharmaceuticals,” current trade agreements “haven’t been negotiated hard enough.”

But the nonprofit Knowledge Ecology International, a group that has frequently weighed in on pharma patent affairs, figures strict IP laws push up costs. Speaking with FiercePharma, KEI director Jamie Love said if Trump is serious about lowering U.S. drug prices, his administration shouldn’t promote high costs around the world.

“They have to take a deep breath and ask themselves, is the U.S. interest equal to pharma’s interest, and we think it is not,” he said.

U.S. concerns have prevailed in some cases. In a move seen as bowing to requests from the Obama Administration, India pledged to abandon its practice of issuing compulsory licenses to introduce cheap generics. That decision came after years of frustration for big drugmakers.

But according to PhRMA's latest commentary, the U.S. drug industry “remains concerned” about India, despite the positive developments there. It’s still worried about an “unpredictable IP environment,” “regulatory data protection failures” and high taxes, among other topics.

Meanwhile, in Canada, PhRMA is “extremely concerned” about new laws that have “created a new and heightened requirement for

patentable utility for pharmaceutical patents.” Such regulations are “both inconsistent with common law and practice in other major countries and unpredictable in practice,” PhRMA said.

In an interview, KEI's Love pointed to Canada's inclusion in PhRMA's list as evidence the "standards are really arbitrary." And in the group's own comments to the USTR, the nonprofit said (PDF) that “policies at USTR are generally lobbyist driven.”

Pushing countries to increase IP protections, and thus drug prices, “would only increase access barriers in foreign countries,” KEI wrote. Instead, “our trading partners could be pressed to match our direct funding and subsidies [for] research and development.”

That, according to KEI, “would lower the net costs of drug development, and would be consistent with the objective of progressively delinking R&D costs from drug prices.”

Colombia made headlines last year when it moved to unilaterally cut the price on Novartis' Glivec through a declaration of public interest following tough negotiations. At the time, leaked memos documented political pressure in Washington, D.C., for Colombian officials to call off the price cut.

KEI previously voiced concerns over the U.S. Army's move to license a Zika vaccine candidate to French drugmaker Sanofi. Before that, the group urged the National Institutes of Health to “break taboo” to exercise march-in rights and reduce drug costs.

EMAIL #2:

Just saw this afternoon that you are appearing at Jamie Love's meeting on the Bayh-Dole panel. Don't mean to be presumptuous, but thought I would pass along some information which might be helpful. Those seeking to misapply the march in provision base their arguments around two phrases in the law-- that when issuing licenses under the march in provision universities do so "**upon terms that are reasonable;**" and in the definitions section which says that "practical application" means that "the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations **available to the public on reasonable terms.**"

The theory of Jamie Love and Rep Doggett is that this language means that such inventions must be available for a "reasonable price."

Here's an article which addresses the first allegation, which is pretty easy as the march in language refers to the terms of the university license, not the terms with which licensor commercializes the invention: <http://www.ipwatchdog.com/2013/11/24/nih-gets-it-right-bayh-dole-is-not-for-price-controls/id=46477/>. It also quotes from Sen. Bayh's statement at NIH when it considered the Norvir march in petition.

The use of the phrase in the definitions section is explained in this article (which shows how the inappropriate use of the march in provision led to the ending of the IPA program and subsequent

passage of Bayh-Dole):
<http://www.ipwatchdog.com/2016/05/02/march-in-rights-health-care-costs/id=68816/>. Towards the end of the article, I address the intended meaning of "available to the public on reasonable terms", which meant that the company was really trying to sell the product rather than stifle its development. As we saw in the last march in petition, Dr Collins said that by their own admission the drug was widely being purchased, so it met the test of the statute.

Finally, you might take a look at Sen. Bayh's statement at the NIH meeting on the Norvir petition: <https://www.ott.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf>. He specifically spells out how the petitioners *deliberately misrepresented the legislative history* to support their theory that Bayh-Dole sanctioned march-ins to control prices. You might also look at Norm Latker's statement made later in the meeting which goes through the meaning of the phrase "reasonable terms" in more detail.

Workshop

History, Experiences, and Prospects of Compulsory Licensing on Medical Patents

in the United States

<http://www.keionline.org/node/271>

7

Date: Friday February 24, 2017

REL0000024733

Location: Kaiser Permanente
Center for Total Health

700 Second St. NE (near Union
Station)

Washington, DC 20002

The event will feature presentations and roundtable discussions and questions and comments from the workshop participants on several topics relating to the non-voluntary use of patents in the United States, with a focus on medical patents.

10 AM: Introduction

10:15 - 10:45

Review of all U.S. legislation proposed, enacted and/or repealed on the compulsory licensing of patents from the 19th Century to the present.

- Zack Struver,
KEI

10:50 - 11:50

A discussion non-voluntary use of patents under 28 USC 1498(a), the statute that covers use of patents "by or for the United States without license of the owner."

- Amy kapczynski,
Professor of Law,
Yale Law School
- Robert
Weissman,
President, Public
Citizen

11:50 AM to 12:30 PM

Lunch

12:30 PM - 1:30 PM

A discussion of the non-voluntary use of patents in court cases involving requests for permanent injunctions as a remedy to infringement, under the standards set out in the by the U.S. Supreme Court in eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006)

- Matthew Herper,
Forbes
- Rachel
Sachs, Associate
Professor at the
Washington
University in St.
Louis School of Law
- Andrew
Goldman, Counsel
for Policy and Legal
Affairs, Knowledge
Ecology International

1:35 PM - 3:00 PM

A discussion of the experience with the Bayh-Dole Act march-in provisions.

- Hanna Vogel,
Legislative
Assistant,
Representative

Doggett, U.S. House
of Representatives

- Richard Wilder, Associate General Counsel in the Global Health Program, the Gates Foundation (May have a travel conflict)
- C. Allen Black, Jr., Ph.D., Adjunct Professor of Law, University of Pittsburgh School of Law. (Counsel for Fabrazyme march-in case).
- James Love, Knowledge Ecology International (KEI)
- Ashley Stevens, President, Focus IP Group (former President of AUTM, the Association of University Technology Managers)

3:00 PM to 3:15 PM

Break

3:15 PM to 3:45 PM A review of global norms and compulsory licensing statutes in selected industrialized countries.

- Frederick M. Abbott, Edward Ball Eminent Scholar Professor of International Law, Florida State

University, College
of Law

- Andrew
Goldman, KEI

3:50 PM to close

A concluding discussion about the need for new statutory authority to grant compulsory licenses on patents, with references to (a) US government negotiations on prices of drugs, (b) the broader need to curb excessive prices of drugs, and (c) the role of compulsory licensing in improving access to research tools, diagnostic tests, and upstream technologies such as CRISPR Genome Editing, and for follow-on inventions.

Starting with initial comments from:

- Aaron S. Kesselheim, MD, JD, MPH, Associate Professor of Medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital. (TBC)
 - Amy kapczynski, Professor of Law, Yale Law School
 - Rachel Sachs, Associate Professor at the Washington University in St. Louis School of Law
 - James Love, KEI
-
- PhRMA, invited
 - (May shuffle this a bit, and perhaps add a few stakeholders)

Sincerely,

Steve

Stephen J. Susalka, Ph.D., CLP

Executive Director

Association of University
Technology Managers (AUTM)

*Advancing Discoveries for a Better
World*

b6

Ssusalka@autm.net

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--
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mwaring@umich.edu

REL0000024733

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From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHExchange/CN=OD/CN=ROHRBAUM]
Sent: 1/12/2017 9:23:25 PM
To: Claire Cassedy [claire.cassedy@keionline.org]
Subject: Re: For Mark

Sorry I was at a meeting and my phone died. Can you call into the number I just sent you now

Sent from my iPhone

On Jan 12, 2017, at 4:22 PM, Claire Cassedy <claire.cassedy@keionline.org> wrote:

Hi Mark,

Left a message on your machine. I'll be around until about 5:30 if you have time to talk. I'm at (202)332-2670. Otherwise, would 2pm tomorrow (Friday) still work for you? I can call you then if so. Thanks for your time!

Best,
Claire

On Thu, Jan 12, 2017 at 1:31 PM, Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@od.nih.gov> wrote:

301-435-4485

From: Claire Cassedy [mailto:claire.cassedy@keionline.org]
Sent: Thursday, January 12, 2017 1:28 PM
To: Jamie Love <james.love@keionline.org>
Cc: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: Re: For Mark

Hi Mark,

Thank you-I can give you a call at 4pm today if it still works for you. What is the best number to reach you at that time?

Best,

Claire

On Thu, Jan 12, 2017 at 1:13 PM, Jamie Love <james.love@keionline.org> wrote:

Thanks Mark. Claire, you can follow up.

On Thu, Jan 12, 2017 at 12:35 PM, Rohrbaugh, Mark (NIH/OD) [E]
<RohrBauM@od.nih.gov> wrote:

Jamie:

I can talk to her and am available today after 3:30 or tomorrow 10-11 or 2-4

Mark

From: jamespackardlove@gmail.com [mailto:jamespackardlove@gmail.com] **On Behalf Of** Jamie Love
Sent: Wednesday, January 11, 2017 2:08 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Claire Cassedy <claire.cassedy@keionline.org>
Subject: For Mark

Mark, is there someone at the NIH that Claire can talk to about the policy on publishing notices about CRADAs?

We were surprised at few notices we found in the Federal Register.

Jamie

--

James Love. Knowledge Ecology International
<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile:
[+41.76.413.6584](tel:+41764136584), twitter.com/jamie_love

--

James Love. Knowledge Ecology International
<http://www.keionline.org/donate.html>

KEI DC tel: [+1.202.332.2670](tel:+12023322670), US Mobile: [+1.202.361.3040](tel:+12023613040), Geneva Mobile:
[+41.76.413.6584](tel:+41764136584), twitter.com/jamie_love

--

Knowledge Ecology International (KEI)

1621 Connecticut Avenue NW

Suite 500

Washington, DC 20009

www.keionline.org

Tel.: [\(202\)332-2670 ext. 11](tel:(202)332-2670)

Fax.: [\(202\)332-2673](tel:(202)332-2673)

--

Knowledge Ecology International (KEI)
1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
www.keionline.org
Tel.: [\(202\)332-2670 ext. 11](tel:(202)332-2670)
Fax.: [\(202\)332-2673](tel:(202)332-2673)

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 10/25/2016 9:14:56 AM
To: Stevens, Ashley J [astevens@bu.edu]
CC: Fred Reinhart (fred@research.umass.edu) [fred@research.umass.edu]
Subject: Re: Publishing the updated drug study

Ashley:

My office is working on a paper on kinase inhibitors starting with Gleevec as a breakthrough. Not focused on source of molecules.

b4

b4

However, if I can be of assistance,

let me know.

Regards,
Mark

Sent from my iPhone

On Oct 25, 2016, at 9:19 AM, Stevens, Ashley J <astevens@bu.edu> wrote:

b4

Best regards,

Ashley

Ashley J. Stevens, D.Phil(Oxon), CLP, RTTP

REL0000024741

<image001.jpg>

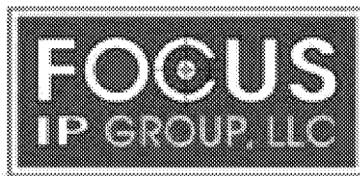
President

70 Yale Street, Suite 100
Winchester, MA 01890-2331

Tel: (781) 721-2670

Cell: b6

astevens@fipgllc.com



From: Rohrbaugh, Mark (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=591AB6B2424B4B8997082718CBB29FAB-ROHRBAUM]
Sent: 6/27/2018 5:10:54 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP /CN=RECIPIENTS/CN=591AB6B2424B4B8997082718CBB29FAB-ROHRBAUM@nih.mail.onmicrosoft.com]
Subject: Re: Prospective Grant of Exclusive License: Production of Monovalent Live Attenuated Zika Vaccines and Multivalent Live Attenuated Flavivirus Vaccines

Is there a call in #?

Sent from my iPhone

On Jun 7, 2018, at 12:36 PM, Rohrbaugh, Mark (NIH/OD) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP /CN=RECIPIENTS/CN=591AB6B2424B4B8997082718CBB29FAB-ROHRBAUM> wrote:

b5

From: Soukas, Peter (NIH/NIAID) [E]
Sent: Thursday, June 07, 2018 12:32 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>
Cc: Frisbie, Suzanne (NIH/NIAID) [E] <Suzanne.Frisbie@nih.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Williams, Richard (NIH/NIAID) [E] <RWILLIAMS@niaid.nih.gov>
Subject: FW: Prospective Grant of Exclusive License: Production of Monovalent Live Attenuated Zika Vaccines and Multivalent Live Attenuated Flavivirus Vaccines

Dear Mark and Mike,

I just received this email from KEI.

b5

b5

b5

Thanks.

Peter Soukas
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Phone: 301-594-8730
Email: ps193c@nih.gov

From: James Love <james.love@keionline.org>
Sent: Thursday, June 7, 2018 12:16 PM
To: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>
Cc: Manon Ress <manon.ress@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; Claire Cassedy <claire.cassedy@keionline.org>
Subject: Prospective Grant of Exclusive License: Production of Monovalent Live Attenuated Zika Vaccines and Multivalent Live Attenuated Flavivirus Vaccines

Peter Soukas, Technology Transfer and Patent Specialist,
Technology Transfer and Intellectual Property Office,
National Institute of Allergy and Infectious Diseases,
National Institutes of Health,
Email:

REL0000024742

ps193c@nih.gov

Dear Peter Soukas,

We are responding to the request for comments on the Prospective Grant of Exclusive License:
Production of Monovalent Live Attenuated Zika Vaccines and Multivalent Live Attenuated Flavivirus
Vaccines, to Medigen Vaccines Biologics Corp. (Medigen), having a place of business in Zhubei, Taiwan.
*

We note the "

The Licensed Territory may be limited to Europe, China, South Korea, Japan, India, Australia
and New Zealand.
"

We oppose granting an exclusive license in the Territory of India, a country with an average
income of \$1,670 in 2016, according to the World Bank. India is also a possible source of the
vaccine for other developing countries, so the granting of an exclusive license may result in
broader restrictions on access.

Sincerely,

James Love
KEI

*

<https://www.federalregister.gov/documents/2018/05/25/2018-11258/prospective-grant-of-exclusive-license-production-of-monovalent-live-attenuated-zika-vaccines-and>

The diagram illustrates a network of collaborations and information flow between various institutions and companies. At the top, BROAD INSTITUTE, HARVARD, and MONSANTO are connected to INTELLA THERAPEUTICS. HARVARD is also connected to EDITAS MEDICINE. BROAD INSTITUTE and MONSANTO are connected to NOVARTIS. EDITAS MEDICINE is connected to CRISPR THERAPEUTICS. CRISPR THERAPEUTICS is connected to BAYER, VERTEX, and UNIVERSITÄT WIEN. VERTEX is connected to TACONIC. TACONIC is connected to CARIBOU BIOSCIENCES. CARIBOU BIOSCIENCES is connected to DU PONT and BERKELEY UNIVERSITY OF CALIFORNIA.

You available to talk at 11? In your office?

Hi Mark:

Renate

REL0000024743

Hi Renate,

I'm planning a piece for Wednesday when Knowledge Ecology International files to ask the federal government to develop a policy to "ensure that the licensing of [the CRISPR] patents is as open and non-discriminatory as possible." (A little more info on this, [via STAT](#).) They plan to do so under laws that would allow the NIH, as a funder of the CRISPR work, to step in if licensing is not happening under reasonable terms. However I know that there is no case in which the federal government has actually exercised that right.

Can the NIH comment on how it will review and respond to this filing? My deadline is EOD today.

Thanks!

Kristen V. Brown
senior writer, gizmodo
949.874.5507

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHExchange/CN=OD/CN=ROHRBAUM]
Sent: 12/21/2016 3:02:52 AM
To: Carr, Sarah (NIH/OD) [E] [/O=NIH/OU=NIHExchange/cn=OD/cn=CARRS]
CC: Paltoo, Dina (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=nhlbios/cn=paltoo]
Subject: Re: Clinical data policy

Thanks. That's all I was thinking about.

Sent from my iPhone

On Dec 20, 2016, at 8:03 PM, Carr, Sarah (NIH/OD) [E] <CarrS@OD.NIH.GOV> wrote:

Mark,

I suppose

b5

b5

Sarah

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, December 20, 2016 2:28 PM
To: Carr, Sarah (NIH/OD) [E] <CarrS@OD.NIH.GOV>; Paltoo, Dina (NIH/OD) [E] <paltoo@od.nih.gov>
Subject: RE: Clinical data policy

b5

From: Carr, Sarah (NIH/OD) [E]
Sent: Tuesday, December 20, 2016 2:08 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Paltoo, Dina (NIH/OD) [E] <paltoo@od.nih.gov>
Subject: RE: Clinical data policy

Mark, can you say more about NIST's draft regs that KEI was commenting on or send a link? And

b5

b5

Sarah

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, December 20, 2016 1:56 PM

REL0000024745

To: Paltoo, Dina (NIH/OD) [E] <paltood@od.nih.gov>; Carr, Sarah (NIH/OD) [E] <CarrS@OD.NIH.GOV>

Subject: Clinical data policy

Dina and Sarah:

NIST received a public response to draft regs from KEI that includes the following

b5

b5

In order to develop more useful evidence to evaluate licensing policies, licenses could and should require transparency of the costs of research and development. For medical inventions, this should include an annual report for R&D outlays, with the company reporting the

following information for each clinical trial that it conducts on the patented invention:

- a. [ClinicalTrials.Gov](https://clinicaltrials.gov) identifier;
- b. Phase;
- c. Conditions;
- d. Interventions;
- e. Title Acronym/Titles;
- f. Outcome Measures;
- g. Sponsor/Collaborators;
- h. Other Study IDs;
- i. Expenditures (for that year);

Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer
Director, Division of Technology Transfer and Innovation Policy
Office of Science Policy
Office of the Director
National Institutes of Health

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 1/28/2017 3:23:27 AM
To: Dodson, Sara (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Dodsonse]
CC: Hsiao, Timothy (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Hsiaoht9d1]
Subject: Re: [Ip-health] Devex: Zika vaccine could be delayed, unaffordable after US Army grants exclusive rights to pharma company

Yes, health plans and state public health programs generally follow CDC recommendations for vaccinations.. More boys for example have been vaccinated with HPV as evidence developed that there are direct benefit to men, not just women, from receiving HPV vaccines. The NIH Lyme disease vaccine never took off because it was not.
"recommended" by CDC.

Sent from my iPhone

> On Jan 27, 2017, at 9:08 PM, Dodson, Sara (NIH/OD) [E] <sara.dodson@nih.gov> wrote:
>
> Thanks for sharing, Mark. My general understanding (and I have to admit not deeply informed by actual data) is that vaccines tend to be pretty cheap. Are there examples of high-cost vaccines not traditionally covered by basic health care plans?
>
> -----Original Message-----
> From: Rohrbaugh, Mark (NIH/OD) [E]
> Sent: Friday, January 27, 2017 5:45 PM
> To: Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Dodson, Sara (NIH/OD) [E] <sara.dodson@nih.gov>; Hsiao, Timothy (NIH/OD) [E] <timothy.hsiao@nih.gov>; Finger, Matthew (NIH/OD) [E] <matthew.finger@nih.gov>; Bochner, David (NIH/OD) [E] <david.bochner@nih.gov>; Volkov, Marina (NIH/OD) [E] <mvolkov@od.nih.gov>
> Subject: FW: [Ip-health] Devex: Zika vaccine could be delayed, unaffordable after US Army grants exclusive rights to pharma company
>
>
>

> -----Original Message-----
> From: Lambert, Richard (NIH/NIAID) [C]
> Sent: Friday, January 27, 2017 12:50 PM
> To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
> Subject: FW: [Ip-health] Devex: Zika vaccine could be delayed, unaffordable after US Army grants exclusive rights to pharma company
>
>
>
> Richard A. Lambert
> Contractor
> National Institute of Allergy and Infectious Diseases National Institutes of Health U.S. Department of Health and Human Services
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> lambertr@niaid.nih.gov
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>
>

> -----Original Message-----
> From: Jamie Love [mailto:james.love@keionline.org]
> Sent: Friday, January 27, 2017 12:44 PM
> To: Zack Struver <zack.struver@keionline.org>; Paul Wilson <pw2101@columbia.edu>
> Cc: Ip-health <ip-health@lists.keionline.org>
> Subject: Re: [Ip-health] Devex: Zika vaccine could be delayed, unaffordable after US Army grants exclusive rights to pharma company
>

> Interesting to hear Paul Wilson's opinions. Does he know much money Sanofi has promised to invest?

> Sanofi

> told Statnews they expected the US government to pay for the late stage trials . Was Sanofi lying then, or now? Sanofi certainly is not paying for the current trials . The Army won't say anything about who will be paying for the future trials, although the NIH is putting out press releases about the six year funding agreement with Sanofi.

>

>

> T

> he 2009 vaccine for Japanese encephalitis that used the same platform as ZPIV wasn't developed a big pharma company, I believe it was registered by I ntercell AG , a firm few have heard of.

> The notion that only a few big companies can make and distribute vaccines is false.

> And in any case, Sanofi has already been given \$43 million to work on this, without a license.

>

> The notion that GAVI is going to protect people in developing countries from price gouging from Sanofi would be more compelling if Sanofi was not

> given exclusive rights. Why give a company a monopoly and then have a

> discussion about the price? And, what about US residents who want to

> avoid having babies with small heads and brain damage? If GAVI going to help them? No.

>

> Jamie

>

>

> On Fri, Jan 27, 2017 at 5:47 PM, Zack Struver <zack.struver@keionline.org>

> wrote:

>

>> <https://www.devex.com/news/zika-vaccine-could-be-delayed-unaffordable-after-us-army-grants-exclusive-rights-to-pharma-company-8951>

>> 9#

>>

>> Zika vaccine could be delayed, unaffordable after US Army grants

>> exclusive rights to pharma company

>>

>> By Sophie Edwards | 27 January 2017

>>

>> The U.S. Army's plan to grant exclusive rights to a promising Zika

>> vaccine to a major pharmaceutical company has raised questions about

>> whether that threatens its future affordability and availability to

>> people in developing countries.

>>

>> The purified, inactivated Zika virus vaccine – called ZP IV – has been

>> developed by the U.S. Army and is currently in its first phase of

>> testing at the Walter Reed Army Institute of Research in Maryland and

>> the National Institutes of Health.

>>

>> If it successfully passes clinical trials, the vaccine would have the

>> potential to halt the spread of the virus, transmitted by mosquitoes

>> and sexual intercourse, which has been reported in 69 countries since

>> 2015, including the United States, and is linked to serious birth

>> defects in children.

>>

>> The deal was posted by the Army on the public Federal Register in

>> December and will give Sanofi Pasteur, the vaccine unit of French

>> multinational pharmaceutical company Sanofi, exclusive access to the

>> new vaccine technology, which has been developed and paid for by the U.S. government.

>> In return, Sanofi will take on the role of conducting clinical trials,

>> getting regulatory approval, manufacturing and distributing the vaccine.

>>

>> The humanitarian aid organization Médecins Sans Frontières has

>> criticized the Army's decision to grant Sanofi the patent license,

>> which will give the company an exclusive right to make, use and sell

>> the vaccine for 20 years, as well as 12 years of marketing and data

>> exclusivity even after the patent has expired. MSF is saying this will

>> give the company a monopoly on the drug and thus no incentive to make

>> it affordable. Sanofi could also choose to stop developing the vaccine

>> if it decides it is commercially unattractive.

>>

>> MSF wants the U.S. Army to consider granting an "open nonexclusive"

>> patent license instead, opening up the technology to other

>> pharmaceutical companies for testing and development. MSF argues this

>> will increase competition and thus bring down the price and ensure the

>> vaccine reaches those who need it in middle-income and developing countries.

>>

>> "Ministries of Health and people around the world will only be able to

>> benefit from the U.S. government investment if the resulting vaccine

>> is effective, safe, available, affordable and suitably adapted to the

>> resource-limited settings where most people affected by Zika virus live,"

>> MSF said in a statement.

>> “The next step in the Zika vaccine development process, including its
>> licensing and technology transfer strategy, needs to ensure that U.S.
>> government funding and leadership in vaccine R&D results in a vaccine
>> that is effective and accessible for all patients in need in the U.S.
>> and globally, including the most neglected,” the group added.

>> The United Nations High Level Panel on Access to Medicines, formed in
>> 2015 to address the lack of access to medicines in many developing
>> countries, appears to agree with MSF’s recommendations. In its 2016
>> report, the panel
>> said: “Universities and research institutions that receive public
>> funding must prioritize public health objectives over financial
>> returns in their patenting and licensing practices,” and listed the
>> use of nonexclusive licenses, the donation of IP rights, and taking
>> part in public sector patent pools as potential mechanisms by which to do this.

>> Sanofi has responded by saying it’s assuming “financial and
>> opportunity risks” by partnering with the government on Zika as there
>> is no guarantee of a commercial market for the vaccine.

>> “...we’re still assuming financial and opportunity risks because there
>> is no clear path to commercialization at this time, as the
>> epidemiology of this infectious disease is still a moving target,”
>> according to Sanofi’s research and development project lead, Jon Heinrichs.

>> The U.S. Army told Devex in an email statement: “We believe granting
>> an exclusive license in this case is reasonable and necessary to most
>> quickly and most safely provide this potential vaccine for public use
>> to combat the growing international threat of the Zika virus.”

>> Unusually, the U.S. Army has requested to extend the time period for
>> comments on the announcement in the Federal Register by an additional
>> 45 days until mid-March, the second time the comment period has been
>> extended, to allow time to compose written responses to the submissions.

>> Experts have predicted the Zika market could be worth more than \$1
>> billion a year, driven by U.S. and European travelers willing to pay
>> high prices for such vaccines, Reuters reported in October.

>> Sanofi is part of a race to develop a Zika vaccine

>> The ZP IV vaccine – which is thought to be the furthest along in terms
>> of development in the Zika vaccine field – is developed from the
>> inactivated Zika virus. The vaccine was shown to give 100 percent
>> protection against the Zika virus in mice, according to a study
>> published in science journal Nature last August.

>> Sanofi is not alone in working on the Zika virus vaccine. It is not
>> even the only drug company to receive U.S. government funding to work
>> on the issue; GlaxoSmithKline has partnered with the NIH to evaluate a
>> new vaccine technology for Zika known as SAM (self-amplifying mRNA),
>> and Japanese company Takeda has also entered the vaccine hunt with
>> \$312 million funding from BARDA.

>> Another group of concerned organizations – including Knowledge Ecology
>> International, a nonprofit that lobbies to increase access to
>> medicines – have also written to the Army to complain about the Sanofi deal.

>> KEI says Sanofi does not need to be incentivized to develop the
>> vaccine and take it to the market – the standard justification for
>> granting such exclusive licenses – since the candidate vaccine has
>> already received “extensive government subsidies” and is extremely
>> likely to get additional funds.

>> “The grant of the exclusive rights in the patent is an unnecessary
>> incentive to bring the invention to practical application because of
>> the significant federal funding in the clinical trials and the grant
>> of additional exclusivities and subsidies,” KEI said.

>> In September, BARDA – the U.S. Biomedical Advanced Research and
>> Development Authority, a unit within the U.S. Department of Health and
>> Human Services – gave Sanofi \$43.2 million “for phase II development
>> and manufacturing” of the Zika vaccine, according to a Sanofi press release.

>> KEI communications and research associate Zack Struver explained that
>> if approved, Sanofi will also earn a priority review voucher from the U.S.
>> Food and Drug Administration, which it could “sell on for millions of

>> dollars," and so already has "sufficient incentive" to develop the
>> vaccine with or without the exclusive license, he said.
>>
>> Priority review vouchers are designed to speed up the review process
>> for new drug products and thus incentivize drug companies to work to
>> develop treatments for rare diseases or those without a robust market.
>> Vouchers are transferable and have been sold to other companies for
>> upwards of \$300 million.
>>
>> However, the statement from the U.S. Army said there was a strong case
>> for granting Sanofi exclusive rights to the technology, due to
>> competition from the "many" groups working on a Zika vaccine. Sanofi
>> is taking on "risk" by accruing the license since there is a "long way
>> to go in terms of time and money" before a Zika vaccine can be
>> approved, they said. Furthermore, the army is also yet to receive the
>> patent from the U.S. Patent and Trademark Office, and there is a
>> chance it "may never issue," adding more "risk" for Sanofi.
>>
>> "The federal government needs a non-federal partner with the research
>> and production capabilities and the willingness to invest their own
>> substantial funding to most quickly get this product to the market and
>> available for public use," the spokesperson added.
>>
>> The KEI letter to the army also asks for four conditions to be imposed
>> on the licensing agreement. These include requiring Sanofi to limit
>> the price of the vaccine to "no more than the median price being
>> charged in other high income countries;" limiting the length of time
>> that Sanofi has exclusive rights to the technology, requiring the
>> vaccine be made "available and affordable" in developing countries;
>> and requiring Sanofi to be transparent about the costs of research and development.
>>
>> The U.S. Army responded by saying the license agreement has
>> stipulations in place to "protect the public interest," including the
>> option to terminate if Sanofi fails to "bring the invention to
>> practical application within a reasonable time," or "make the benefits
>> of the invention reasonably accessible to the public."
>>
>> Sanofi says no "clear path to commercialization" for Zika at this time
>>
>> The pharmaceutical company says that even with the public funding from
>> BARDA, taking ZP IV through the many stages of testing, approval and
>> manufacturing requires Sanofi to take on "financial and opportunity risks"
>> due to the fact Zika is "still a moving target" and there is "no clear
>> path to commercialization at this time," according to Heinrichs,
>> Sanofi's research and development project lead.
>>
>> "We have modeled various commercial scenarios including current
>> endemic areas, spread to other geographies and the travel market,
>> among others. The nature of the epidemiology and spread of the virus
>> will impact the degree of profitability," Heinrichs said.
>>
>> Sanofi may have a point, according to Paul Wilson, assistant professor
>> of clinical population and family health at Columbia University's
>> Mailman School of Public Health, who says there is "genuine uncertainty"
>> surrounding how big the Zika problem will be and how widely a vaccine
>> would be used. This is compounded, he said, by the fact that the virus
>> could ultimately become widespread but "without causing harm," or even
>> die out as people become immune.
>>
>> If this turns out to be the case, however, MSF's and KEI's concerns
>> may be valid since Sanofi would likely lose interest in the project
>> and fail to drive the vaccine all the way through development, Wilson said.
>>
>> "I'm sympathetic to MSF's position - when you have a vaccine being
>> developed with public funding and you give the rights to one firm, you
>> have every right to put in place conditions to make sure vaccine will
>> be available to all who need it," he said.
>>
>> "The U.S. government has to at least justify why an exclusive license
>> is necessary," Wilson added.
>>
>> Sanofi could be the best company for the job
>>
>> The company has experience with vaccines against viruses in the same
>> family as Zika, known as flaviviruses, having developed vaccines for
>> Japanese encephalitis and dengue fever.
>>
>> This could explain why the U.S. Army is keen to entrust the Zika virus

>> vaccine to Sanofi, which is an established player and one with a track
>> record of supplying vaccines to developing countries, according to Wilson.
>>
>> "It is still more or less true that only the big multinational
>> pharmaceutical companies have ever been able to successfully bring a
>> truly new vaccine to market. Even when you have a vaccine candidate
>> that's at the stage of this Zika one is now, there are still many
>> challenges involved in the later stages of development," he said.
>>
>> However, the capacity of pharmaceutical firms in India, Brazil and
>> China to develop vaccines is "growing rapidly" and some of these firms
>> could probably bring the vaccine to market, although perhaps not as
>> rapidly as a multinational, Wilson said.
>>
>> The vaccine industry has long been dominated by four major
>> multinational pharmaceutical companies – GlaxoSmithKline, Merck,
>> Sanofi-Pasteur, and Pfizer, which accounted for approximately 86
>> percent of global vaccine revenue in 2015. Their monopoly is
>> attributed to entry barriers such as high start-up costs and long lead
>> times; vaccines can take anywhere from 10 to 16 years to reach the market, preventing other companies
from competing.
>>
>> Phase III trials are technically difficult to conduct and many drugs
>> and vaccines fail them, and developing a robust manufacturing process
>> is "very technical" and is subject to "stringent regulatory
>> requirements," which can be hard to navigate, Wilson explained.
>>
>> "The U.S. Army may want a MNC partner because they believe that is the
>> surest way to ensure that the vaccine gets developed quickly. There
>> are only a few companies out there that have the relevant experience
>> and have shown an active interest in developing country markets, which
>> Sanofi has demonstrated," he said.
>>
>> Access will not be an issue in the poorest countries if GAVI steps in
>>
>> In relation to MSF's and KEI's concerns about access to the vaccine,
>> if approved, GAVI, the Vaccine Alliance – a partnership of major
>> donors and pharmaceutical companies designed to ensure access to
>> vaccines for children in developing countries – could support
>> low-income countries in purchasing the vaccine, Wilson said.
>>
>> Sanofi confirmed in an email to Devex that it has worked with GAVI on
>> distribution of vaccines in the past, and so working with the alliance
>> on the Zika vaccine was "certainly a possibility," but that a strategy
>> for "pricing and distribution" would be developed later in the process.
>>
>> However, the real problem of access will be in middle-income
>> countries, such as Brazil, which are ineligible for GAVI funding but
>> where the vaccine is urgently needed.
>>
>> "Sanofi doesn't see a market in the poorest countries and so they're
>> happy to provide vaccines at a reasonable price there through GAVI,
>> since it would be seen as bad PR not to. But they are not necessarily
>> prepared to make those concessions in places like Brazil and India,
>> where the greatest access concerns would be," Wilson said.
>>
>> Sanofi has bad track record when it comes to serving developing
>> countries, MSF says
>>
>> MSF spoke out against Sanofi in 2015 after the company decided to stop
>> manufacturing a pan-African snakebite antivenom because it was no
>> longer lucrative, leaving a gap in supplies that MSF said would be
>> likely to lead to unnecessary deaths.
>>
>> The NGO is worried that if given the exclusive license for the Zika
>> vaccine, the pharmaceutical company will follow the same path and
>> neglect countries with great need but less opportunities for profit,
>> according to Judit Rius Sanjuan, MSF's U.S. access campaign manager.
>>
>> Instead, Sanjuan wants the U.S. Army to offer Sanofi a nonexclusive
>> license, which she argued would be "better public policy," ensure the
>> Zika virus has broader geographical scope, and protects the U.S.
>> government from "having all its apples in one basket."
>>
>> There are other ways to get medicines through development and into
>> markets
>>
>> There have been successful examples of the U.S. government offering

>> nonexclusive licenses for patented technologies through the United Nations backed Medicines Patent Pool, a global health financing mechanism set up in 2010 to share drug technology and research to speed up development, lower costs and increase access to newer HIV/AIDS, viral hepatitis C, and tuberculosis treatments in developing countries.

>> MPP works by signing agreements with patent holders – such as the NIH and the U.S. Army but also nonprofits, pharmaceutical companies and individuals – to create a pool of relevant patents. The partners are then licensed to generic drug manufacturers who can then produce generic versions of the medicines, often utilizing more than one patented technology in the process of development.

>> For example, in 2010, the NIH licensed a patent on Darunavir to the MPP, which spurred the development of a new combination drug. Furthermore, Johns Hopkins University announced on Jan. 25 that it is licensing its patent for the drug candidate sunitinib, which could be used to treat melanoma, exclusively to the MPP.

>> While the MPP does not currently work on vaccines, and so licensing to the MPP was not an option for the U.S. Army, these examples set a “good precedent” for “innovative” nonexclusive licensing agreements and how effectively sharing research can expedite research and development, increase collaboration, and diversify the medicine development process, MSF’s Sanjuan said.

>> Furthermore, there have been other notable examples of the U.S. granting nonexclusive licenses for the development of vaccines. For example, the human-bovine rotavirus vaccine technology was licensed by the NIH to eight organizations, one in the United States and seven in the developing countries, to manufacture and distribute the rotavirus vaccine.

>> --

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>>

>>

>> --

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From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 12/20/2016 12:13:55 PM
To: Leff, Michelle (NIH/NIDA/IRP) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIDAIntra/cn=MLeff]
Subject: Re: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits
Attachments: image008.jpg; image002.jpg; image009.jpg; image010.jpg; image005.jpg; image011.jpg; image007.jpg

Thx. Better than some other media, and they included important points we made but still do not present equally the opposing view that march in is not an authority to control prices.

Sent from my iPhone

On Dec 20, 2016, at 7:10 AM, Leff, Michelle (NIH/NIDA/IRP) [E] <MLeff@intra.nida.nih.gov> wrote:

Just finished reading the article with my morning coffee. Congratulations on the interview. Were you pleased with the coverage?

M

Michelle Kim Leff, MD, MBA
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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, December 20, 2016 7:06 AM
To: NIH TDC Long <niaaattcdcl@mail.nih.gov>; OD-OTT <OD-OTT@OD.NIH.GOV>
Subject: Fwd: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

Sent from my iPhone

Begin forwarded message:

From: "Myles, Renate (NIH/OD) [E]" <mylesr@od.nih.gov>
Date: December 19, 2016 at 9:33:05 PM EST
To: "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>, NIH Director's Executive Committee <OD-SmallStaff@mail.nih.gov>
Cc: "Jackson, Calvin (NIH/OD) [E]" <JACKSONC@od31tm1.od.nih.gov>, OCPLPressTeam <OCPLPressTeam@od.nih.gov>, "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>, "Kassilke, Deborah (NIH/OD) [E]" <deborah.kassilke@nih.gov>
Subject: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

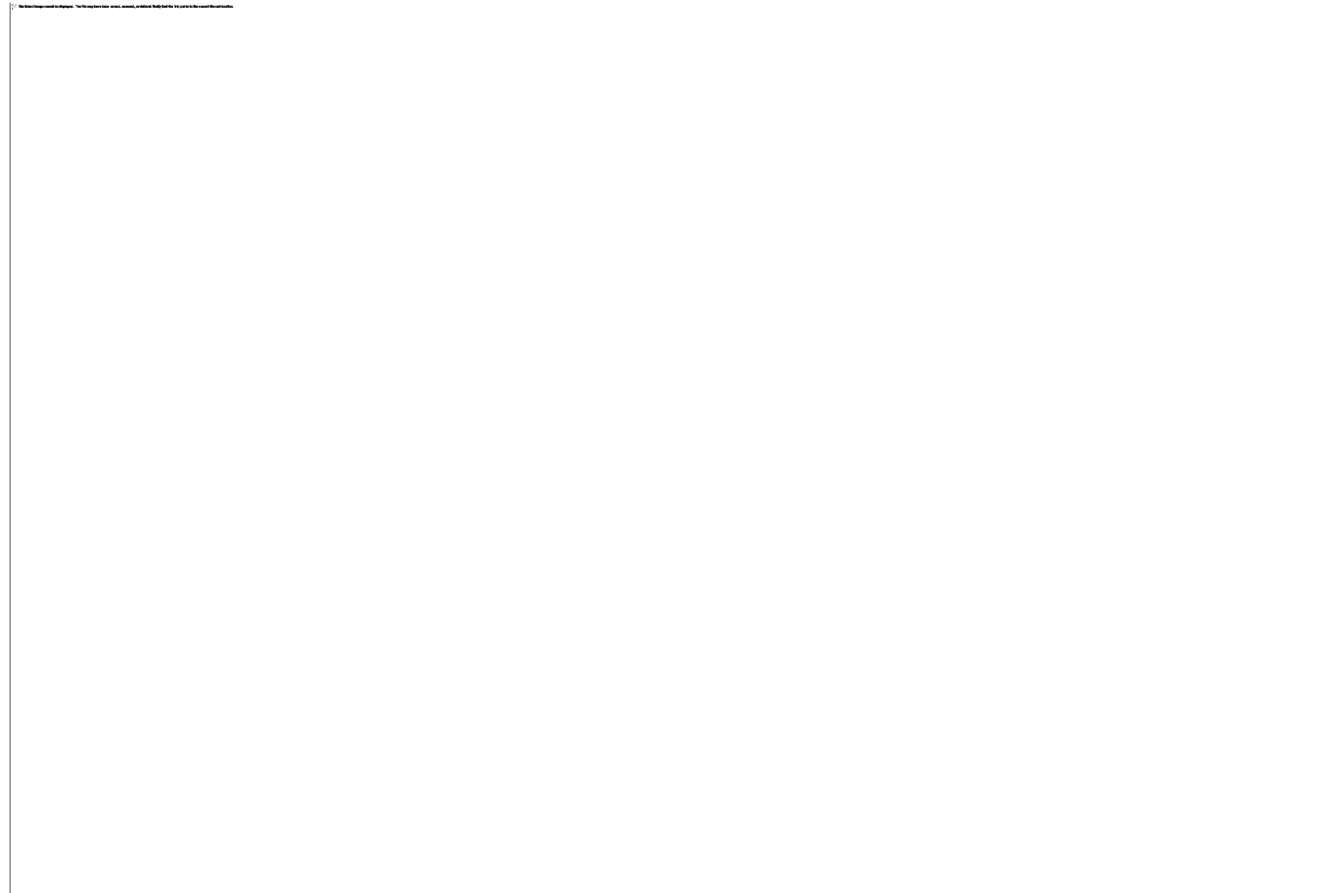
REL0000024749

New York Times

Health

Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

By MATT RICHTEL and ANDREW POLLACK DEC. 19, 2016



Dr. Steven Rosenberg, left, who has led the surgery branch at the National Cancer Institute for 42 years, and Dr. Arie Belldegrun, the founder of Kite Pharma. Credit Jesse Dittmar (left) and Emily Berl (right) for The New York Times

Enthusiasm for cancer immunotherapy is soaring, and so is Arie Belldegrun's fortune.

Dr. Belldegrun, a physician, co-founded Kite Pharma, a company that could be the first to market next year with a highly anticipated new immunotherapy treatment. But even without a product, Dr. Belldegrun has struck gold.

His stock in Kite is worth about \$170 million. Investors have profited along with him, as the company's share price has soared to about \$50 from an initial price of \$17 in 2014.

The results reflect widespread excitement over immunotherapy, which harnesses the body's immune system to attack cancer and has rescued some patients from near-certain death. But they also speak volumes about the value of Kite's main scientific partner: the United States government.

Kite's treatment, a form of immunotherapy called CAR-T, was initially developed by a team of researchers at the National Cancer Institute, led by a longtime friend and mentor of Dr. Beldegrun. Now Kite pays several million a year to the government to support continuing research dedicated to the company's efforts.

The relationship puts American taxpayers squarely in the middle of one of the hottest new drug markets. It also raises a question: Are taxpayers getting a good deal?

Defenders say that the partnership will likely bring a lifesaving treatment to patients, something the government cannot really do by itself, and that that is what matters most.

Critics say that taxpayers will end up paying twice for the same drug — once to support its development and a second time to buy it — while the company reaps the financial benefit.

“If this was not a government-funded cancer treatment — if it was for a new solar technology, for example — it would be scandalous to think that some private investors are reaping massive profits off a taxpayer-funded invention,” said James Love, director of Knowledge Ecology International, an advocacy group concerned with access to medicines.

Photo



Dr. Rosenberg and Dr. Belldégrun in the mid-1980s. Dr. Belldégrun became a research fellow for Dr. Rosenberg at the cancer institute in 1985. Credit Kite Pharma

The debate goes squarely to one of the nation's most vexing challenges: rising health care and drug prices. Kite is one of a growing number of drug and biotech companies relying on federal laboratories. Analysts expect the company to charge at least \$200,000 for the new treatment, which is intended as a one-time therapy for patients.

While the law allows the government to demand drug-price concessions from its private-sector partners, the government has declined to do so with Kite and generally disdains the practice.

Insisting on lower prices, federal researchers say, would drive away innovative partners that speed the drug-development process and benefit patients. But with the government doing so much pivotal research, others say that the private sector cannot afford to walk away.

"The market is so reliant on the knowledge and know-how that comes out of the government and academic labs," said Dr. Aaron Kesselheim, director of the Program on Regulation, Therapeutics and Law at Brigham & Women's Hospital in Boston.

Price curbs, he said, "would not suddenly lead to a total abandonment of this pipeline. It couldn't possibly."

Drug makers would be especially unlikely to turn away from immunotherapy, where the promising science has set off a "gold rush mentality," according to Mark Edwards of Bioscience Advisors, a company which tracks pharmaceutical licensing deals.

The National Institutes of Health, the parent agency of the National Cancer Institute, currently has about 400 cooperative research agreements with companies, and licenses hundreds of patented inventions for private-sector development.

Kite executives and national health officials characterize their partnership as a model arrangement in a system established by Congress three decades ago. The system has given birth to the cancer drug Taxol, the AIDS drug Prezista, two cervical cancer vaccines and a widely used test for H.I.V. infection, among other innovations.

Continue reading the main story
Photo

Dr. Rosenberg in his lab at the cancer institute in Bethesda, Md. Partnerships between government labs and drug companies are “absolutely essential or many discoveries will not see the light of day,” he said. Credit Jesse Dittmar for The New York Times

Kite’s first drug, called KTE-C19, could help thousands of patients each year in the United States with certain blood cancers. If it succeeds, it could generate sales of \$1 billion to \$2 billion annually, according to Wall Street analysts, making it among the most lucrative drugs to come from government research.

But the government’s share of any Kite success would be modest, much lower than some academic research groups have wrangled in immunotherapy deals worth hundreds of millions of dollars. Federal officials counter that the reward to the taxpayer is not money but the drug itself.

“This is exactly the way things should work,” said Dr. Steven Rosenberg, who has led the surgery branch at the National Cancer Institute for 42 years and led development of Kite’s drug. Such partnerships, he said, are “absolutely essential or many discoveries will not see the light of day.”

Moreover, government officials say, companies in such deals must take significant financial risks and expenditures on their own, without any guarantee that the drug will be approved.

Kite says it has spent more than \$200 million on research and development, including running larger clinical trials than those conducted by the cancer

institute, and recently spent about \$30 million to build a factory that will be able to make treatments for up to 5,000 patients a year.

Setting the price of the drug, Dr. Rosenberg said, “is for the marketplace.”

A Public-Private Partnership

Like many business deals, this one began with a personal relationship — in this case between Dr. Rosenberg and Dr. Belldégrun.

After finishing medical school in his native Israel, performing surgery in helicopters for the Israeli armed forces, and completing residency at Brigham & Women’s Hospital, Dr. Belldégrun became a research fellow for Dr. Rosenberg at the N.C.I. It was 1985, and Dr. Belldégrun was put to work on a new project of Dr. Rosenberg’s — extracting tumor-fighting immune cells from cancer patients, multiplying them in the laboratory, and putting them back in.

“He was one of the more outstanding fellows to come through,” said Dr. Rosenberg, 76, who is widely considered a cancer research luminary.

Continue reading the main story

Photo

Dr. Belldégrun, center, at the Nasdaq stock exchange, where Kite Pharma is listed. The company was founded in 2009 and went public in 2014. Credit Nasdaq, 2016

When the fellowship ended in 1988, Dr. Belldgrun became a prominent surgeon at the University of California, Los Angeles, but the two men stayed in touch. Eventually, Dr. Belldgrun, 67, got the entrepreneurial bug. He co-founded a biotech company, Agensys, which was acquired by a bigger company for more than \$500 million. He was also involved with Cougar Biotechnology, which developed the prostate cancer drug Zytiga and was acquired by Johnson & Johnson for \$1 billion in May 2009. A month later, Dr. Belldgrun formed Kite with a group of colleagues and investors to pursue cancer immunotherapy.

That same month, a Florida marine contractor named Eric Karlson, whose non-Hodgkin's lymphoma was advancing despite four prior treatments, became the first patient treated by Dr. Rosenberg with what would eventually become KTE-C19. The treatment entailed removing some of Mr. Karlson's immune system T cells from his blood, genetically engineering them to recognize and fight his cancer, multiplying the T cells to huge numbers in the laboratory and transferring them back into his body. After two such treatments, Mr. Karlson remains alive and cancer-free eight years later.

Kite initially thought it would pursue an approach to immunotherapy known as cancer vaccines, but in 2010, Dr. Belldgrun visited Dr. Rosenberg and was shown the X-rays of Mr. Karlson and of a second patient.

Dr. Belldgrun was bowled over. "I had no doubt that this is going to be a drug and, more than that, it will become a platform for multiple products," he recalled. "We never looked back."

Over the next two years, the National Cancer Institute worked out a deal with Kite that was signed in 2012. It was the first of eight contracts between the government and the company that generally take two forms.

In one type of contract, Kite licenses patented inventions and agrees to pay the government royalties, roughly 5 percent of sales of any commercial product arising from a particular patent. However, there is no such license specifically for KTE-C19 because the underlying treatment was not patented by the N.C.I., so royalties will be minimal.

Officials say the agency did not apply for a patent because the treatment was similar to what others had been developing. Also, at the time the treatment was first created, in 2007, immunotherapy was considered to have dim commercial prospects.

"Back then, we didn't even think about commercial aspects," said Dr. James N. Kochenderfer, a scientist at the agency who designed the treatment when working in Dr. Rosenberg's group.

Under the second type of contract, known as a cooperative research and development agreement, Kite provides money to the N.C.I. to support research. Kite is now paying \$3 million a year to Dr. Rosenberg's lab and has provided \$7.5 million to it in total since 2012. Based on its regulatory filings, Kite is paying \$7.8 million a year for research agreements and licenses in total, with at least \$4

million of that going to the cancer institute and the rest to academic or corporate partners.

The taxpayer has invested, too. Dr. Rosenberg estimated that the government has spent roughly \$10 million over the years on what has become KTE-C19. He said Kite's \$3 million a year is about equal to the taxpayer funding in that area and has helped speed research.

These days, researchers from Kite and the cancer institute, typically including Dr. Rosenberg and Dr. Belldgrun, confer by conference call every other Thursday for 90 minutes. Kite employees have spent long periods at the N.C.I., learning how to manufacture the therapy and how to treat patients in advance with chemotherapy.

"We shouldn't underestimate the value and the importance of N.I.H., not only to Kite but to the whole field of engineered T-cell therapy," Dr. Belldgrun said. When Kite signed its first deal with the cancer agency, he said, it "tapped into six years of monumental work that they had done."

Some immunotherapy competitors marvel at the company's coup in tapping into the agency's expertise. "They got 20 years of research all together in one scoop," said Dr. Carlos Paya, chief executive of Immune Design, which is pursuing a different approach.

But government officials say few, if any, other companies were interested in the technology at the time Dr. Belldgrun came calling. Dr. Rosenberg said that before Kite, a few companies, including Johnson & Johnson, had looked at an earlier version of his technology but were wary because treatment involved processing each patient's cells.

Government-developed technology available to be licensed to companies is posted on the website of the National Institutes of Health. And when the agency intends to grant a license to a particular company, it publishes that in the Federal Register, inviting public comment and possible competing offers. Both steps were taken in the case of Kite, officials said.

Kite did not get everything the cancer institute has developed in the field. Some other companies, including Opus Bio and Bluebird Bio, got rights to some products, in part because the companies had special expertise that the agency's researchers desired. But Kite seems to have gotten the balance of them and N.C.I. technology accounts for the majority of its pipeline of possible products, though the company is diversifying.

Photo

A slide that Kite Pharma used in presentations to potential investors pointed out the company's relationship with Dr. Rosenberg.

Dr. Rosenberg professes no interest in the business side of the Kite relationship. He does not own stock in any company, even Kite, though he could get up to \$150,000 a year in patent royalties if some of Kite's efforts pay off.

Dr. Belldgrun, in contrast to his mentor, has commercial flair. He is known for his sharp business suits, lives in the Bel-Air neighborhood of Los Angeles, and seems as comfortable on Wall Street or in high society as in the operating room.

Kite's relationship with the N.C.I. is an important part of its appeal to investors. In some presentations, Dr. Belldgrun has shown a photograph of himself with Dr. Rosenberg in their younger days. And he persuaded Dr. Rosenberg to speak at Kite's first big meeting for investors in June 2015, the only time he has ever spoken to Wall Street.

In emails obtained through a Freedom of Information Act request by Knowledge Ecology International, Dr. Belldgrun praised Dr. Rosenberg's talk and sent him copies of investment reports from the conference written by Wall Street analysts.

"Thank you for making the effort to come to NY," Dr. Belldgrun wrote. "I heard only raving reviews about your presence and presentation."

A 'Reasonable' Question

The reliance of private companies on government-funded research goes well beyond obvious cases like Kite. In many instances, companies work with universities or medical centers that, in turn, have been funded from the \$32 billion annual budget of the National Institutes of Health.

Kite's two main competitors, Novartis and Juno Therapeutics, for instance, derived similar immunotherapy treatments largely from academic institutions, developed at least in part with government funding. Novartis has a relationship with the University of Pennsylvania, and Juno with the Memorial Sloan Kettering Cancer Center, the Fred Hutchinson Cancer Research Center and Seattle Children's Hospital.

"For the most important drugs you'll see some public-sector involvement," said Bhaven Sampat, an associate professor of health policy and management at Columbia University. He was one author of a study that found that 9 percent of all drugs approved between 1988 and 2005 were based directly on a patent held by the public sector. But 47.8 percent of the drugs relied at least indirectly on some federally funded research.

Continue reading the main story

Photo

Eric Karlson at his home on Marco Island, Fla., this month. Mr. Karlson's non-Hodgkin's lymphoma was successfully treated by Dr. Rosenberg with what would eventually become KTE-C19. Credit Scott McIntyre for The New York Times

The figures were higher for more medically important drugs: 17.4 percent had a direct public-sector patent, while 64.5 percent had at least an indirect public-sector influence.

These figures are up sharply from before the 1980s. Such partnerships and licensing deals were encouraged by the 1980 Bayh-Dole and Stevenson-Wydler Acts, and the 1986 Federal Technology Transfer Act. The laws are credited with jump-starting the biotechnology industry.

But from the beginning, some people questioned whether taxpayers were getting a bad deal.

Perhaps the best-known drug developed from a cooperative research and development agreement — the cancer drug Taxol — was the subject of several congressional hearings in the early 1990s that investigated whether the drug's maker, Bristol-Myers Squibb, charged too much and whether the government recouped enough of its investment. In the end, the pricing was left unchanged.

The N.I.H. argues that if it imposes pricing restrictions, it won't get partners. In fact, in 1995, it struck from its negotiating tactics a goal that prices be "reasonable."

"Companies will not take technologies from us if we say the government will decide in the future what the price will be," said Mark Rohrbaugh, who ran the technology transfer office at the institutes from 2001 to 2013 and is now an adviser to the agency. After the "reasonable price" clause was struck, he said, there was a threefold increase in partnership deals.

The N.I.H. can collect royalties from successful products to help offset the costs of the research, but so far these royalties have been small, amounting to an estimated \$135 million in the last fiscal year from 870 licenses, with the bulk of the money coming from a small number of drugs.

"We're not preoccupied with financial value," Dr. Rohrbaugh said. "Our mission is treatment of people and improving public health."

In that regard, the government's bet on a small company like Kite, which might have seemed risky, appears to be paying off so far. Dr. Belldegrün has largely delivered on promises to raise money, assemble an experienced staff, build the factory, conduct clinical trials and begin to apply for regulatory approval. Once considered the underdog to Novartis and Juno, Kite might be the first reach the market.

Photo

Scans of Mr. Karlson's body before and after his treatment. In the cross-sections on the left, the arrows point to signs of lymphoma in areas such as his armpits, chest, spleen and pelvis. Credit National Cancer Institute

Academic centers and companies often drive harder bargains in licensing technology. In some cases, academic centers own a stake in a company they license technology to, allowing them to reap a financial windfall if the company does well. Both the Hutchinson cancer center and Sloan Kettering have owned stock in Juno and are entitled to substantial payments — up to \$350 million and \$150 million — if Juno's stock reaches certain levels.

The N.I.H. does not take equity positions in companies to avoid an appearance of a conflict of interest. So to critics of the government deals, drug prices are crucial to understanding taxpayer value. After all, they ask, is a drug truly widely available — which is what the government says is its measure of success — if it costs too much for some people?

Rachel Sachs, an associate law professor at Washington University in St. Louis and expert in innovation policy, said the government had every right to seek price concessions. She noted that the government, through Medicare and Medicaid, was effectively buying its inventions back from itself. "The public is paying for the research and to the extent that many people, if not most, will pay through public insurance, we're paying again," she said.

Hillary Clinton, in her campaign for president, promised to set new rules for federal support of research so that Americans “get the value they deserve” for the money taxpayers spend in supporting research. It is not clear how President-elect Donald J. Trump will approach these issues; he has said he favors reducing health care costs, but Republicans, who control Congress, too, have opposed government involvement in price setting.

One mechanism to control pricing already exists. It is called march-in rights, and it lets the N.I.H. take back control of a patent on an invention made with federal funding if the drug is not being made available to the public on reasonable terms. The tool has gone unused.

Earlier this year, Knowledge Ecology International and another advocacy group, the Union for Affordable Cancer Treatment, petitioned the agency to exercise march-in rights on Xtandi, a prostate cancer drug that was developed by federally funded researchers at U.C.L.A. It said the price in the United States of about \$129,000 a year, two to four times that in other developed countries, meant the drug was not reasonably available. The effort was supported by other public interest groups and some Democratic members of Congress.

U.C.L.A. made more than \$500 million by selling its royalty rights to the drug. But the N.I.H. declined to exercise its march-in rights on Xtandi, arguing that it was not qualified to judge whether a drug’s price is reasonable and that a high price does not mean a drug is not being made available to the public.

“N.I.H. has made it clear that its job is not to decide prices of drugs, period,” Dr. Rohrbaugh said

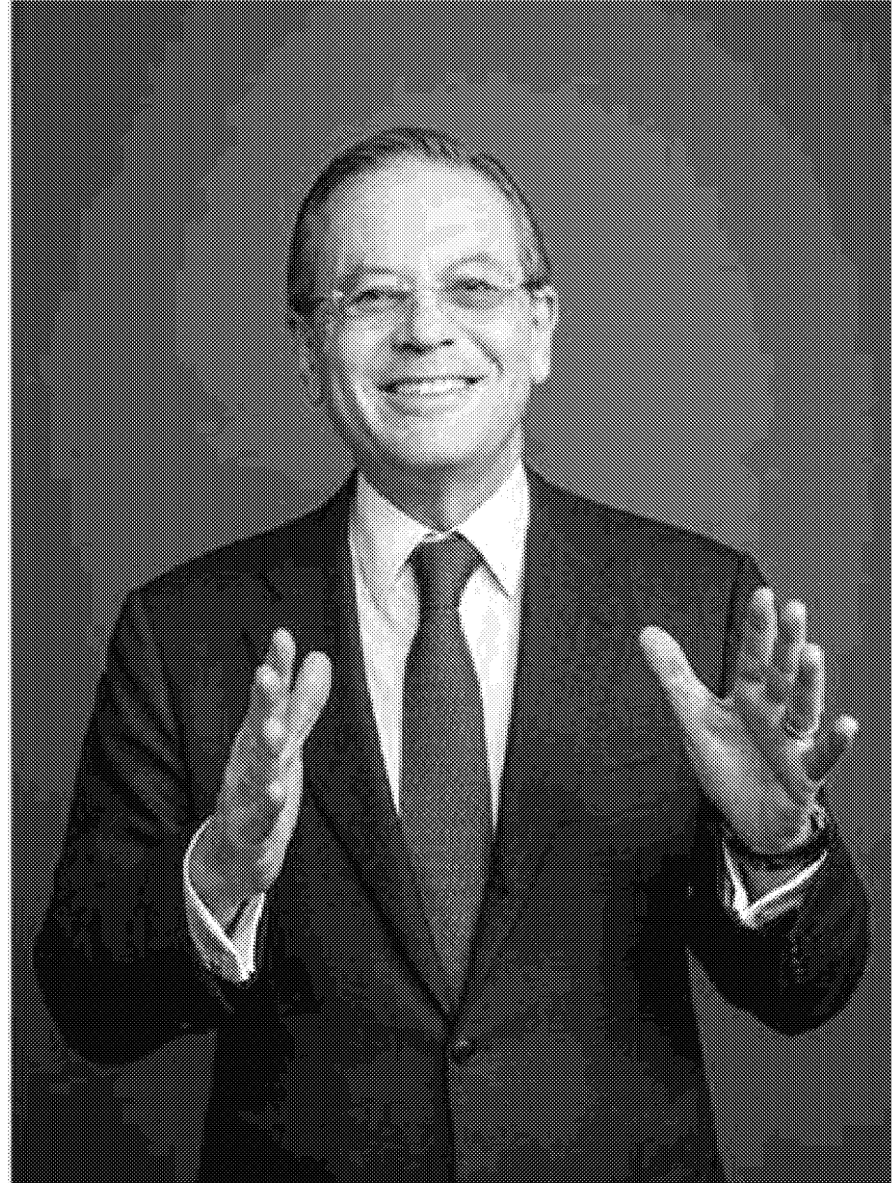
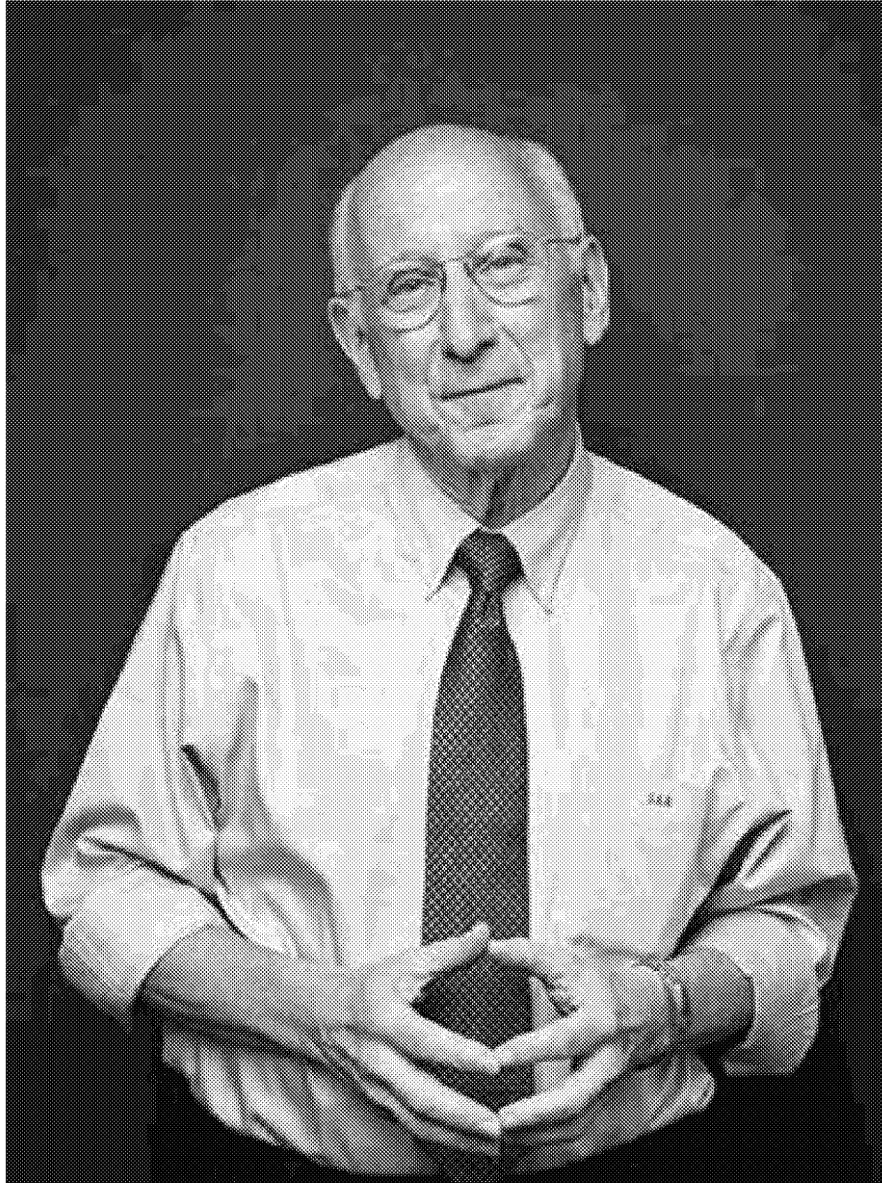
Kite says it has not decided what to charge for KTE-C19, but Dr. Belldegrun hinted that Kite’s therapy might be relatively expensive because ideally it would be a single treatment that would cure the patient, not a drug that would have to be taken continuously. He added that Kite would take steps to make sure that everyone who needed the drug could get it.

Meantime, the relationship between Kite and the National Cancer Institute is expanding to develop treatments for other cancers, including one technique Dr. Rosenberg thinks could be used to attack solid tumors like colon, breast and lung cancer.

“The potential for broad applicability is huge,” he said.

That could mean many lives saved and maybe more billion-dollar drugs for Kite and its investors, with the American taxpayer right in the middle of the deal.

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From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/OD/CN=ROHRBAUM]
Sent: 1/30/2017 2:38:24 AM
To: Dodson, Sara (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Dodsonse]
CC: Hsiao, Timothy (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Hsiaoht9d1]
Subject: Re: [Ip-health] Devex: Zika vaccine could be delayed, unaffordable after US Army grants exclusive rights to pharma company

Regardless of the cost, vaccines don't make much money because the market is often small and erratic. Unless the vaccine is mandatory, usually the uptake is low and most vaccines are only given in one course unlike most other drugs. With Zika, who knows what the market will be, especially if the efficacy is not high--you might only vaccinate high risk areas and not all travelers for example.

Sent from my iPhone

> On Jan 27, 2017, at 9:08 PM, Dodson, Sara (NIH/OD) [E] <sara.dodson@nih.gov> wrote:

>
> Thanks for sharing, Mark. My general understanding (and I have to admit not deeply informed by actual data) is that vaccines tend to be pretty cheap. Are there examples of high-cost vaccines not traditionally covered by basic health care plans?

>
> -----Original Message-----
> From: Rohrbaugh, Mark (NIH/OD) [E]
> Sent: Friday, January 27, 2017 5:45 PM
> To: Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Dodson, Sara (NIH/OD) [E] <sara.dodson@nih.gov>; Hsiao, Timothy (NIH/OD) [E] <timothy.hsiao@nih.gov>; Finger, Matthew (NIH/OD) [E] <matthew.finger@nih.gov>; Bochner, David (NIH/OD) [E] <david.bochner@nih.gov>; Volkov, Marina (NIH/OD) [E] <mvolkov@od.nih.gov>
> Subject: FW: [Ip-health] Devex: Zika vaccine could be delayed, unaffordable after US Army grants exclusive rights to pharma company

>
>
>
> -----Original Message-----
> From: Lambert, Richard (NIH/NIAID) [C]
> Sent: Friday, January 27, 2017 12:50 PM
> To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
> Subject: FW: [Ip-health] Devex: Zika vaccine could be delayed, unaffordable after US Army grants exclusive rights to pharma company

>
>
> Richard A. Lambert
> Contractor
> National Institute of Allergy and Infectious Diseases National Institutes of Health U.S. Department of Health and Human Services
> 5601 Fishers Lane, Rm. 2G47, MSC 9804
> Bethesda, MD 20892-9804
> (Courier: Rockville, MD. 20852)
> 301.496.2644 main officeline
> 240.627.3706 direct line
> FAX 240.627.3117
> lambertr@niaid.nih.gov
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>
>
> -----Original Message-----
> From: Jamie Love [mailto:james.love@keionline.org]
> Sent: Friday, January 27, 2017 12:44 PM
> To: Zack Struver <zack.struver@keionline.org>; Paul Wilson <pw2101@columbia.edu>
> Cc: Ip-health <ip-health@lists.keionline.org>
> Subject: Re: [Ip-health] Devex: Zika vaccine could be delayed, unaffordable after US Army grants exclusive rights to pharma company

>
> Interesting to hear Paul Wilson's opinions. Does he know much money Sanofi has promised to invest?

> Sanofi
> told Statnews they expected the US government to pay for the late stage trials . Was Sanofi lying then, or now? Sanofi certainly is not paying for the current trials . The Army won't say anything about who will be paying for the future trials, although the NIH is putting out press releases about the six year funding agreement with Sanofi.
>
>
> T
> he 2009 vaccine for Japanese encephalitis that used the same platform as ZPIV wasn't developed a big pharma company, I believe it was registered by InterCell AG , a firm few have heard of.
> The notion that only a few big companies can make and distribute vaccines is false.
> And in any case, Sanofi has already been given \$43 million to work on this, without a license.
>
> The notion that GAVI is going to protect people in developing countries from price gouging from Sanofi would be more compelling if Sanofi was not
> given exclusive rights. Why give a company a monopoly and then have a
> discussion about the price? And, what about US residents who want to
> avoid having babies with small heads and brain damage? If GAVI going to help them? No.
>
> Jamie
>
>
> On Fri, Jan 27, 2017 at 5:47 PM, Zack Struver <zack.struver@keionline.org>
> wrote:
>
>> <https://www.devex.com/news/zika-vaccine-could-be-delayed-unaffordable-after-us-army-grants-exclusive-rights-to-pharma-company-8951>
>> 9#
>>
>> Zika vaccine could be delayed, unaffordable after US Army grants
>> exclusive rights to pharma company
>>
>> By Sophie Edwards | 27 January 2017
>>
>> The U.S. Army's plan to grant exclusive rights to a promising Zika
>> vaccine to a major pharmaceutical company has raised questions about
>> whether that threatens its future affordability and availability to
>> people in developing countries.
>>
>> The purified, inactivated Zika virus vaccine – called ZP IV – has been
>> developed by the U.S. Army and is currently in its first phase of
>> testing at the Walter Reed Army Institute of Research in Maryland and
>> the National Institutes of Health.
>>
>> If it successfully passes clinical trials, the vaccine would have the
>> potential to halt the spread of the virus, transmitted by mosquitoes
>> and sexual intercourse, which has been reported in 69 countries since
>> 2015, including the United States, and is linked to serious birth
>> defects in children.
>>
>> The deal was posted by the Army on the public Federal Register in
>> December and will give Sanofi Pasteur, the vaccine unit of French
>> multinational pharmaceutical company Sanofi, exclusive access to the
>> new vaccine technology, which has been developed and paid for by the U.S. government.
>> In return, Sanofi will take on the role of conducting clinical trials,
>> getting regulatory approval, manufacturing and distributing the vaccine.
>>
>> The humanitarian aid organization Médecins Sans Frontières has
>> criticized the Army's decision to grant Sanofi the patent license,
>> which will give the company an exclusive right to make, use and sell
>> the vaccine for 20 years, as well as 12 years of marketing and data
>> exclusivity even after the patent has expired. MSF is saying this will
>> give the company a monopoly on the drug and thus no incentive to make
>> it affordable. Sanofi could also choose to stop developing the vaccine
>> if it decides it is commercially unattractive.
>>
>> MSF wants the U.S. Army to consider granting an "open nonexclusive"
>> patent license instead, opening up the technology to other
>> pharmaceutical companies for testing and development. MSF argues this
>> will increase competition and thus bring down the price and ensure the
>> vaccine reaches those who need it in middle-income and developing countries.
>>
>> "Ministries of Health and people around the world will only be able to
>> benefit from the U.S. government investment if the resulting vaccine
>> is effective, safe, available, affordable and suitably adapted to the
>> resource-limited settings where most people affected by Zika virus live,"
>> MSF said in a statement.
>>

>> "The next step in the Zika vaccine development process, including its
>> licensing and technology transfer strategy, needs to ensure that U.S.
>> government funding and leadership in vaccine R&D results in a vaccine
>> that is effective and accessible for all patients in need in the U.S.
>> and globally, including the most neglected," the group added.
>>
>> The United Nations High Level Panel on Access to Medicines, formed in
>> 2015 to address the lack of access to medicines in many developing
>> countries, appears to agree with MSF's recommendations. In its 2016
>> report, the panel
>> said: "Universities and research institutions that receive public
>> funding must prioritize public health objectives over financial
>> returns in their patenting and licensing practices," and listed the
>> use of nonexclusive licenses, the donation of IP rights, and taking
>> part in public sector patent pools as potential mechanisms by which to do this.
>>
>> Sanofi has responded by saying it's assuming "financial and
>> opportunity risks" by partnering with the government on Zika as there
>> is no guarantee of a commercial market for the vaccine.
>>
>> "...we're still assuming financial and opportunity risks because there
>> is no clear path to commercialization at this time, as the
>> epidemiology of this infectious disease is still a moving target,"
>> according to Sanofi's research and development project lead, Jon Heinrichs.
>>
>> The U.S. Army told Devex in an email statement: "We believe granting
>> an exclusive license in this case is reasonable and necessary to most
>> quickly and most safely provide this potential vaccine for public use
>> to combat the growing international threat of the Zika virus."
>>
>> Unusually, the U.S. Army has requested to extend the time period for
>> comments on the announcement in the Federal Register by an additional
>> 45 days until mid-March, the second time the comment period has been
>> extended, to allow time to compose written responses to the submissions.
>>
>> Experts have predicted the Zika market could be worth more than \$1
>> billion a year, driven by U.S. and European travelers willing to pay
>> high prices for such vaccines, Reuters reported in October.
>>
>> Sanofi is part of a race to develop a Zika vaccine
>>
>> The ZP IV vaccine – which is thought to be the furthest along in terms
>> of development in the Zika vaccine field – is developed from the
>> inactivated Zika virus. The vaccine was shown to give 100 percent
>> protection against the Zika virus in mice, according to a study
>> published in science journal Nature last August.
>>
>> Sanofi is not alone in working on the Zika virus vaccine. It is not
>> even the only drug company to receive U.S. government funding to work
>> on the issue; GlaxoSmithKline has partnered with the NIH to evaluate a
>> new vaccine technology for Zika known as SAM (self-amplifying mRNA),
>> and Japanese company Takeda has also entered the vaccine hunt with
>> \$312 million funding from BARDA.
>>
>> Another group of concerned organizations – including Knowledge Ecology
>> International, a nonprofit that lobbies to increase access to
>> medicines – have also written to the Army to complain about the Sanofi deal.
>>
>> KEI says Sanofi does not need to be incentivized to develop the
>> vaccine and take it to the market – the standard justification for
>> granting such exclusive licenses – since the candidate vaccine has
>> already received "extensive government subsidies" and is extremely
>> likely to get additional funds.
>>
>> "The grant of the exclusive rights in the patent is an unnecessary
>> incentive to bring the invention to practical application because of
>> the significant federal funding in the clinical trials and the grant
>> of additional exclusivities and subsidies," KEI said.
>>
>> In September, BARDA – the U.S. Biomedical Advanced Research and
>> Development Authority, a unit within the U.S. Department of Health and
>> Human Services – gave Sanofi \$43.2 million "for phase II development
>> and manufacturing" of the Zika vaccine, according to a Sanofi press release.
>>
>> KEI communications and research associate Zack Struver explained that
>> if approved, Sanofi will also earn a priority review voucher from the U.S.
>> Food and Drug Administration, which it could "sell on for millions of
>> dollars," and so already has "sufficient incentive" to develop the

>> vaccine with or without the exclusive license, he said.

>>

>> Priority review vouchers are designed to speed up the review process

>> for new drug products and thus incentivize drug companies to work to

>> develop treatments for rare diseases or those without a robust market.

>> Vouchers are transferable and have been sold to other companies for

>> upwards of \$300 million.

>>

>> However, the statement from the U.S. Army said there was a strong case

>> for granting Sanofi exclusive rights to the technology, due to

>> competition from the "many" groups working on a Zika vaccine. Sanofi

>> is taking on "risk" by accruing the license since there is a "long way

>> to go in terms of time and money" before a Zika vaccine can be

>> approved, they said. Furthermore, the army is also yet to receive the

>> patent from the U.S. Patent and Trademark Office, and there is a

>> chance it "may never issue," adding more "risk" for Sanofi.

>>

>> "The federal government needs a non-federal partner with the research

>> and production capabilities and the willingness to invest their own

>> substantial funding to most quickly get this product to the market and

>> available for public use," the spokesperson added.

>>

>> The KEI letter to the army also asks for four conditions to be imposed

>> on the licensing agreement. These include requiring Sanofi to limit

>> the price of the vaccine to "no more than the median price being

>> charged in other high income countries;" limiting the length of time

>> that Sanofi has exclusive rights to the technology, requiring the

>> vaccine be made "available and affordable" in developing countries;

>> and requiring Sanofi to be transparent about the costs of research and development.

>>

>> The U.S. Army responded by saying the license agreement has

>> stipulations in place to "protect the public interest," including the

>> option to terminate if Sanofi fails to "bring the invention to

>> practical application within a reasonable time," or "make the benefits

>> of the invention reasonably accessible to the public."

>>

>> Sanofi says no "clear path to commercialization" for Zika at this time

>>

>> The pharmaceutical company says that even with the public funding from

>> BARDA, taking ZP IV through the many stages of testing, approval and

>> manufacturing requires Sanofi to take on "financial and opportunity risks"

>> due to the fact Zika is "still a moving target" and there is "no clear

>> path to commercialization at this time," according to Heinrichs,

>> Sanofi's research and development project lead.

>>

>> "We have modeled various commercial scenarios including current

>> endemic areas, spread to other geographies and the travel market,

>> among others. The nature of the epidemiology and spread of the virus

>> will impact the degree of profitability," Heinrichs said.

>>

>> Sanofi may have a point, according to Paul Wilson, assistant professor

>> of clinical population and family health at Columbia University's

>> Mailman School of Public Health, who says there is "genuine uncertainty"

>> surrounding how big the Zika problem will be and how widely a vaccine

>> would be used. This is compounded, he said, by the fact that the virus

>> could ultimately become widespread but "without causing harm," or even

>> die out as people become immune.

>>

>> If this turns out to be the case, however, MSF's and KEI's concerns

>> may be valid since Sanofi would likely lose interest in the project

>> and fail to drive the vaccine all the way through development, Wilson said.

>>

>> "I'm sympathetic to MSF's position - when you have a vaccine being

>> developed with public funding and you give the rights to one firm, you

>> have every right to put in place conditions to make sure vaccine will

>> be available to all who need it," he said.

>>

>> "The U.S. government has to at least justify why an exclusive license

>> is necessary," Wilson added.

>>

>> Sanofi could be the best company for the job

>>

>> The company has experience with vaccines against viruses in the same

>> family as Zika, known as flaviviruses, having developed vaccines for

>> Japanese encephalitis and dengue fever.

>>

>> This could explain why the U.S. Army is keen to entrust the Zika virus

>> vaccine to Sanofi, which is an established player and one with a track

>> record of supplying vaccines to developing countries, according to Wilson.
>>
>> "It is still more or less true that only the big multinational
>> pharmaceutical companies have ever been able to successfully bring a
>> truly new vaccine to market. Even when you have a vaccine candidate
>> that's at the stage of this Zika one is now, there are still many
>> challenges involved in the later stages of development," he said.
>>
>> However, the capacity of pharmaceutical firms in India, Brazil and
>> China to develop vaccines is "growing rapidly" and some of these firms
>> could probably bring the vaccine to market, although perhaps not as
>> rapidly as a multinational, Wilson said.
>>
>> The vaccine industry has long been dominated by four major
>> multinational pharmaceutical companies – GlaxoSmithKline, Merck,
>> Sanofi-Pasteur, and Pfizer, which accounted for approximately 86
>> percent of global vaccine revenue in 2015. Their monopoly is
>> attributed to entry barriers such as high start-up costs and long lead
>> times; vaccines can take anywhere from 10 to 16 years to reach the market, preventing other companies
from competing.
>>
>> Phase III trials are technically difficult to conduct and many drugs
>> and vaccines fail them, and developing a robust manufacturing process
>> is "very technical" and is subject to "stringent regulatory
>> requirements," which can be hard to navigate, Wilson explained.
>>
>> "The U.S. Army may want a MNC partner because they believe that is the
>> surest way to ensure that the vaccine gets developed quickly. There
>> are only a few companies out there that have the relevant experience
>> and have shown an active interest in developing country markets, which
>> Sanofi has demonstrated," he said.
>>
>> Access will not be an issue in the poorest countries if GAVI steps in
>>
>> In relation to MSF's and KEI's concerns about access to the vaccine,
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>> individuals – to create a pool of relevant patents. The partners are
>> then licensed to generic drug manufacturers who can then produce
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>> While the MPP does not currently work on vaccines, and so licensing to
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>> “good precedent” for “innovative” nonexclusive licensing agreements
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>> --
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> http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org

From: Rohrbach, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 1/30/2017 2:28:39 AM
To: Dodson, Sara (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Dodsonse]
Subject: Re: [Ip-health] Devex: Zika vaccine could be delayed, unaffordable after US Army grants exclusive rights to pharma company

Depends on the vaccine, live attenuated, denatured, component protein.

Sent from my iPhone

> On Jan 27, 2017, at 9:08 PM, Dodson, Sara (NIH/OD) [E] <sara.dodson@nih.gov> wrote:
>
> Thanks for sharing, Mark. My general understanding (and I have to admit not deeply informed by actual data) is that vaccines tend to be pretty cheap. Are there examples of high-cost vaccines not traditionally covered by basic health care plans?
>
> -----Original Message-----
> From: Rohrbach, Mark (NIH/OD) [E]
> Sent: Friday, January 27, 2017 5:45 PM
> To: Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Dodson, Sara (NIH/OD) [E] <sara.dodson@nih.gov>; Hsiao, Timothy (NIH/OD) [E] <timothy.hsiao@nih.gov>; Finger, Matthew (NIH/OD) [E] <matthew.finger@nih.gov>; Bochner, David (NIH/OD) [E] <david.bochner@nih.gov>; Volkov, Marina (NIH/OD) [E] <mvolkov@od.nih.gov>
> Subject: FW: [Ip-health] Devex: Zika vaccine could be delayed, unaffordable after US Army grants exclusive rights to pharma company
>
>
>
> -----Original Message-----
> From: Lambert, Richard (NIH/NIAID) [C]
> Sent: Friday, January 27, 2017 12:50 PM
> To: Rohrbach, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
> Subject: FW: [Ip-health] Devex: Zika vaccine could be delayed, unaffordable after US Army grants exclusive rights to pharma company
>
>
>
> Richard A. Lambert
> Contractor
> National Institute of Allergy and Infectious Diseases National Institutes of Health U.S. Department of Health and Human Services
> 5601 Fishers Lane, Rm. 2G47, MSC 9804
> Bethesda, MD 20892-9804
> (Courier: Rockville, MD. 20852)
> 301.496.2644 main officeline
> 240.627.3706 direct line
> FAX 240.627.3117
> lambertr@niaid.nih.gov
> This message is intended for the exclusive use of the recipient(s) identified above. The information in this email and any of its attachments may be confidential and/or sensitive and should not be retained, disseminated, distributed or copied by or to persons not authorized to receive such information. If you receive this message in error please inform the sender and delete it immediately from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any unauthorized statements made by the sender in this message.
>
>
> -----Original Message-----
> From: Jamie Love [mailto:james.love@keionline.org]
> Sent: Friday, January 27, 2017 12:44 PM
> To: Zack Struver <zack.struver@keionline.org>; Paul Wilson <pw2101@columbia.edu>
> Cc: Ip-health <ip-health@lists.keionline.org>
> Subject: Re: [Ip-health] Devex: Zika vaccine could be delayed, unaffordable after US Army grants exclusive rights to pharma company
>
> Interesting to hear Paul Wilson's opinions. Does he know much money Sanofi has promised to invest?
> Sanofi
> told Statnews they expected the US government to pay for the late stage trials . Was Sanofi lying then, or now? Sanofi certainly is not paying for the current trials . The Army won't say anything about who will be paying for the future trials, although the NIH is putting out press releases about the six year funding agreement with Sanofi.
>

>
> T
> he 2009 vaccine for Japanese encephalitis that used the same platform as ZPIV wasn't developed a big pharma company, I believe it was registered by InterCell AG, a firm few have heard of.
> The notion that only a few big companies can make and distribute vaccines is false.
> And in any case, Sanofi has already been given \$43 million to work on this, without a license.
>
> The notion that GAVI is going to protect people in developing countries from price gouging from Sanofi would be more compelling if Sanofi was not
> given exclusive rights. Why give a company a monopoly and then have a
> discussion about the price? And, what about US residents who want to
> avoid having babies with small heads and brain damage? If GAVI going to help them? No.
>
> Jamie
>
>
> On Fri, Jan 27, 2017 at 5:47 PM, Zack Struver <zack.struver@keionline.org>
> wrote:
>
>> <https://www.devex.com/news/zika-vaccine-could-be-delayed-unaffordable-after-us-army-grants-exclusive-rights-to-pharma-company-8951>
>> 9#
>>
>> Zika vaccine could be delayed, unaffordable after US Army grants
>> exclusive rights to pharma company
>>
>> By Sophie Edwards | 27 January 2017
>>
>> The U.S. Army's plan to grant exclusive rights to a promising Zika
>> vaccine to a major pharmaceutical company has raised questions about
>> whether that threatens its future affordability and availability to
>> people in developing countries.
>>
>> The purified, inactivated Zika virus vaccine — called ZPIV — has been
>> developed by the U.S. Army and is currently in its first phase of
>> testing at the Walter Reed Army Institute of Research in Maryland and
>> the National Institutes of Health.
>>
>> If it successfully passes clinical trials, the vaccine would have the
>> potential to halt the spread of the virus, transmitted by mosquitoes
>> and sexual intercourse, which has been reported in 69 countries since
>> 2015, including the United States, and is linked to serious birth
>> defects in children.
>>
>> The deal was posted by the Army on the public Federal Register in
>> December and will give Sanofi Pasteur, the vaccine unit of French
>> multinational pharmaceutical company Sanofi, exclusive access to the
>> new vaccine technology, which has been developed and paid for by the U.S. government.
>> In return, Sanofi will take on the role of conducting clinical trials,
>> getting regulatory approval, manufacturing and distributing the vaccine.
>>
>> The humanitarian aid organization Médecins Sans Frontières has
>> criticized the Army's decision to grant Sanofi the patent license,
>> which will give the company an exclusive right to make, use and sell
>> the vaccine for 20 years, as well as 12 years of marketing and data
>> exclusivity even after the patent has expired. MSF is saying this will
>> give the company a monopoly on the drug and thus no incentive to make
>> it affordable. Sanofi could also choose to stop developing the vaccine
>> if it decides it is commercially unattractive.
>>
>> MSF wants the U.S. Army to consider granting an "open nonexclusive"
>> patent license instead, opening up the technology to other
>> pharmaceutical companies for testing and development. MSF argues this
>> will increase competition and thus bring down the price and ensure the
>> vaccine reaches those who need it in middle-income and developing countries.
>>
>> "Ministries of Health and people around the world will only be able to
>> benefit from the U.S. government investment if the resulting vaccine
>> is effective, safe, available, affordable and suitably adapted to the
>> resource-limited settings where most people affected by Zika virus live,"
>> MSF said in a statement.
>>
>> "The next step in the Zika vaccine development process, including its

>> licensing and technology transfer strategy, needs to ensure that U.S. government funding and leadership in vaccine R&D results in a vaccine that is effective and accessible for all patients in need in the U.S. and globally, including the most neglected," the group added.

>> The United Nations High Level Panel on Access to Medicines, formed in 2015 to address the lack of access to medicines in many developing countries, appears to agree with MSF's recommendations. In its 2016 report, the panel said: "Universities and research institutions that receive public funding must prioritize public health objectives over financial returns in their patenting and licensing practices," and listed the use of nonexclusive licenses, the donation of IP rights, and taking part in public sector patent pools as potential mechanisms by which to do this.

>> Sanofi has responded by saying it's assuming "financial and opportunity risks" by partnering with the government on Zika as there is no guarantee of a commercial market for the vaccine.

>> "...we're still assuming financial and opportunity risks because there is no clear path to commercialization at this time, as the epidemiology of this infectious disease is still a moving target," according to Sanofi's research and development project lead, Jon Heinrichs.

>> The U.S. Army told Devex in an email statement: "We believe granting an exclusive license in this case is reasonable and necessary to most quickly and most safely provide this potential vaccine for public use to combat the growing international threat of the Zika virus."

>> Unusually, the U.S. Army has requested to extend the time period for comments on the announcement in the Federal Register by an additional 45 days until mid-March, the second time the comment period has been extended, to allow time to compose written responses to the submissions.

>> Experts have predicted the Zika market could be worth more than \$1 billion a year, driven by U.S. and European travelers willing to pay high prices for such vaccines, Reuters reported in October.

>> Sanofi is part of a race to develop a Zika vaccine

>> The ZP IV vaccine — which is thought to be the furthest along in terms of development in the Zika vaccine field — is developed from the inactivated Zika virus. The vaccine was shown to give 100 percent protection against the Zika virus in mice, according to a study published in science journal Nature last August.

>> Sanofi is not alone in working on the Zika virus vaccine. It is not even the only drug company to receive U.S. government funding to work on the issue; GlaxoSmithKline has partnered with the NIH to evaluate a new vaccine technology for Zika known as SAM (self-amplifying mRNA), and Japanese company Takeda has also entered the vaccine hunt with \$312 million funding from BARDA.

>> Another group of concerned organizations — including Knowledge Ecology International, a nonprofit that lobbies to increase access to medicines — have also written to the Army to complain about the Sanofi deal.

>> KEI says Sanofi does not need to be incentivized to develop the vaccine and take it to the market — the standard justification for granting such exclusive licenses — since the candidate vaccine has already received "extensive government subsidies" and is extremely likely to get additional funds.

>> "The grant of the exclusive rights in the patent is an unnecessary

>> incentive to bring the invention to practical application because of
>> the significant federal funding in the clinical trials and the grant
>> of additional exclusivities and subsidies," KEI said.
>>
>> In September, BARDA — the U.S. Biomedical Advanced Research and
>> Development Authority, a unit within the U.S. Department of Health and
>> Human Services — gave Sanofi \$43.2 million "for phase II development
>> and manufacturing" of the Zika vaccine, according to a Sanofi press release.
>>
>> KEI communications and research associate Zack Struver explained that
>> if approved, Sanofi will also earn a priority review voucher from the U.S.
>> Food and Drug Administration, which it could "sell on for millions of
>> dollars," and so already has "sufficient incentive" to develop the
>> vaccine with or without the exclusive license, he said.
>>
>> Priority review vouchers are designed to speed up the review process
>> for new drug products and thus incentivize drug companies to work to
>> develop treatments for rare diseases or those without a robust market.
>> Vouchers are transferable and have been sold to other companies for
>> upwards of \$300 million.
>>
>> However, the statement from the U.S. Army said there was a strong case
>> for granting Sanofi exclusive rights to the technology, due to
>> competition from the "many" groups working on a Zika vaccine. Sanofi
>> is taking on "risk" by accruing the license since there is a "long way
>> to go in terms of time and money" before a Zika vaccine can be
>> approved, they said. Furthermore, the army is also yet to receive the
>> patent from the U.S. Patent and Trademark Office, and there is a
>> chance it "may never issue," adding more "risk" for Sanofi.
>>
>> "The federal government needs a non-federal partner with the research
>> and production capabilities and the willingness to invest their own
>> substantial funding to most quickly get this product to the market and
>> available for public use," the spokesperson added.
>>
>> The KEI letter to the army also asks for four conditions to be imposed
>> on the licensing agreement. These include requiring Sanofi to limit
>> the price of the vaccine to "no more than the median price being
>> charged in other high income countries;" limiting the length of time
>> that Sanofi has exclusive rights to the technology, requiring the
>> vaccine be made "available and affordable" in developing countries;
>> and requiring Sanofi to be transparent about the costs of research and development.
>>
>> The U.S. Army responded by saying the license agreement has
>> stipulations in place to "protect the public interest," including the
>> option to terminate if Sanofi fails to "bring the invention to
>> practical application within a reasonable time," or "make the benefits
>> of the invention reasonably accessible to the public."
>>
>> Sanofi says no "clear path to commercialization" for Zika at this time
>>
>> The pharmaceutical company says that even with the public funding from
>> BARDA, taking ZP IV through the many stages of testing, approval and
>> manufacturing requires Sanofi to take on "financial and opportunity risks"
>> due to the fact Zika is "still a moving target" and there is "no clear
>> path to commercialization at this time," according to Heinrichs,
>> Sanofi's research and development project lead.
>>
>> "We have modeled various commercial scenarios including current
>> endemic areas, spread to other geographies and the travel market,

>> among others. The nature of the epidemiology and spread of the virus
>> will impact the degree of profitability," Heinrichs said.
>>
>> Sanofi may have a point, according to Paul Wilson, assistant professor
>> of clinical population and family health at Columbia University's
>> Mailman School of Public Health, who says there is "genuine uncertainty"
>> surrounding how big the Zika problem will be and how widely a vaccine
>> would be used. This is compounded, he said, by the fact that the virus
>> could ultimately become widespread but "without causing harm," or even
>> die out as people become immune.
>>
>> If this turns out to be the case, however, MSF's and KEI's concerns
>> may be valid since Sanofi would likely lose interest in the project
>> and fail to drive the vaccine all the way through development, Wilson said.
>>
>> "I'm sympathetic to MSF's position — when you have a vaccine being
>> developed with public funding and you give the rights to one firm, you
>> have every right to put in place conditions to make sure vaccine will
>> be available to all who need it," he said.
>>
>> "The U.S. government has to at least justify why an exclusive license
>> is necessary," Wilson added.
>>
>> Sanofi could be the best company for the job
>>
>> The company has experience with vaccines against viruses in the same
>> family as Zika, known as flaviviruses, having developed vaccines for
>> Japanese encephalitis and dengue fever.
>>
>> This could explain why the U.S. Army is keen to entrust the Zika virus
>> vaccine to Sanofi, which is an established player and one with a track
>> record of supplying vaccines to developing countries, according to Wilson.
>>
>> "It is still more or less true that only the big multinational
>> pharmaceutical companies have ever been able to successfully bring a
>> truly new vaccine to market. Even when you have a vaccine candidate
>> that's at the stage of this Zika one is now, there are still many
>> challenges involved in the later stages of development," he said.
>>
>> However, the capacity of pharmaceutical firms in India, Brazil and
>> China to develop vaccines is "growing rapidly" and some of these firms
>> could probably bring the vaccine to market, although perhaps not as
>> rapidly as a multinational, Wilson said.
>>
>> The vaccine industry has long been dominated by four major
>> multinational pharmaceutical companies — GlaxoSmithKline, Merck,
>> Sanofi-Pasteur, and Pfizer, which accounted for approximately 86
>> percent of global vaccine revenue in 2015. Their monopoly is
>> attributed to entry barriers such as high start-up costs and long lead
>> times; vaccines can take anywhere from 10 to 16 years to reach the market, preventing other companies
>> from competing.
>>
>> Phase III trials are technically difficult to conduct and many drugs
>> and vaccines fail them, and developing a robust manufacturing process
>> is "very technical" and is subject to "stringent regulatory
>> requirements," which can be hard to navigate, Wilson explained.
>>
>> "The U.S. Army may want a MNC partner because they believe that is the
>> surest way to ensure that the vaccine gets developed quickly. There
>> are only a few companies out there that have the relevant experience
>> and have shown an active interest in developing country markets, which
>> Sanofi has demonstrated," he said.
>>
>> Access will not be an issue in the poorest countries if GAVI steps in
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>> the developing countries, to manufacture and distribute the rotavirus vaccine.

>>

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>> org

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From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHExchange/CN=OD/CN=ROHRBAUM]
Sent: 12/20/2016 12:02:15 PM
To: Myles, Renate (NIH/OD) [E] [/O=NIH/OU=NIHExchange/cn=recipients/cn=mylesr]
Subject: Re: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

I read it quickly [b5] I will take a fresh look this morning.

Sent from my iPhone

On Dec 19, 2016, at 9:29 PM, Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov> wrote:

Would you agree that [b5]

[b5]

From: Myles, Renate (NIH/OD) [E]

Sent: Monday, December 19, 2016 8:59 PM

To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>

Subject: RE: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

I think [b5]

[b5]

I thought they [b5]

[b5]

From: Rohrbaugh, Mark (NIH/OD) [E]

Sent: Monday, December 19, 2016 8:58 PM

To: Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>

Subject: Re: NYT: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

[b5]

Sent from my iPhone

On Dec 19, 2016, at 7:48 PM, Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov> wrote:

Haven't read it yet, but wanted you to take a look. I'll share more broadly when I'm home.

Health

Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

By MATT RICHTEL and ANDREW POLLACK DEC. 19, 2016

<image001.jpg>

Dr. Steven Rosenberg, left, who has led the surgery branch at the National Cancer Institute for 42 years, and Dr. Arie Belldegrun, the founder of Kite Pharma. Credit Jesse Dittmar (left) and Emily Berl (right) for The New York Times
Enthusiasm for cancer immunotherapy is soaring, and so is Arie Belldegrun's fortune.

Dr. Belldgrun, a physician, co-founded Kite Pharma, a company that could be the first to market next year with a highly anticipated new immunotherapy treatment. But even without a product, Dr. Belldgrun has struck gold. His stock in Kite is worth about \$170 million. Investors have profited along with him, as the company's share price has soared to about \$50 from an initial price of \$17 in 2014.

The results reflect widespread excitement over immunotherapy, which harnesses the body's immune system to attack cancer and has rescued some patients from near-certain death. But they also speak volumes about the value of Kite's main scientific partner: the United States government.

Kite's treatment, a form of immunotherapy called CAR-T, was initially developed by a team of researchers at the National Cancer Institute, led by a longtime friend and mentor of Dr. Belldgrun. Now Kite pays several million a year to the government to support continuing research dedicated to the company's efforts. The relationship puts American taxpayers squarely in the middle of one of the hottest new drug markets. It also raises a question: Are taxpayers getting a good deal?

Defenders say that the partnership will likely bring a lifesaving treatment to patients, something the government cannot really do by itself, and that that is what matters most.

Critics say that taxpayers will end up paying twice for the same drug — once to support its development and a second time to buy it — while the company reaps the financial benefit.

"If this was not a government-funded cancer treatment — if it was for a new solar technology, for example — it would be scandalous to think that some private investors are reaping massive profits off a taxpayer-funded invention," said James Love, director of Knowledge Ecology International, an advocacy group concerned with access to medicines.

Photo

<image002.jpg>

Dr. Rosenberg and Dr. Belldgrun in the mid-1980s. Dr. Belldgrun became a research fellow for Dr. Rosenberg at the cancer institute in 1985. Credit Kite Pharma

The debate goes squarely to one of the nation's most vexing challenges: rising health care and drug prices. Kite is one of a growing number of drug and biotech companies relying on federal laboratories. Analysts expect the company to charge at least \$200,000 for the new treatment, which is intended as a one-time therapy for patients.

While the law allows the government to demand drug-price concessions from its private-sector partners, the government has declined to do so with Kite and generally disdains the practice.

Insisting on lower prices, federal researchers say, would drive away innovative partners that speed the drug-development process and benefit patients. But with the government doing so much pivotal research, others say that the private sector cannot afford to walk away.

"The market is so reliant on the knowledge and know-how that comes out of the government and academic labs," said Dr. Aaron Kesselheim, director of the Program on Regulation, Therapeutics and Law at Brigham & Women's Hospital in Boston.

Price curbs, he said, "would not suddenly lead to a total abandonment of this pipeline. It couldn't possibly."

Drug makers would be especially unlikely to turn away from immunotherapy, where the promising science has set off a “gold rush mentality,” according to Mark Edwards of Bioscience Advisors, a company which tracks pharmaceutical licensing deals.

The National Institutes of Health, the parent agency of the National Cancer Institute, currently has about 400 cooperative research agreements with companies, and licenses hundreds of patented inventions for private-sector development.

Kite executives and national health officials characterize their partnership as a model arrangement in a system established by Congress three decades ago. The system has given birth to the cancer drug Taxol, the AIDS drug Prezista, two cervical cancer vaccines and a widely used test for H.I.V. infection, among other innovations.

Continue reading the main story

Photo

<image003.jpg>

Dr. Rosenberg in his lab at the cancer institute in Bethesda, Md. Partnerships between government labs and drug companies are “absolutely essential or many discoveries will not see the light of day,” he said. Credit Jesse Dittmar for The New York Times

Kite’s first drug, called KTE-C19, could help thousands of patients each year in the United States with certain blood cancers. If it succeeds, it could generate sales of \$1 billion to \$2 billion annually, according to Wall Street analysts, making it among the most lucrative drugs to come from government research.

But the government’s share of any Kite success would be modest, much lower than some academic research groups have wrangled in immunotherapy deals worth hundreds of millions of dollars. Federal officials counter that the reward to the taxpayer is not money but the drug itself.

“This is exactly the way things should work,” said Dr. Steven Rosenberg, who has led the surgery branch at the National Cancer Institute for 42 years and led development of Kite’s drug. Such partnerships, he said, are “absolutely essential or many discoveries will not see the light of day.”

Moreover, government officials say, companies in such deals must take significant financial risks and expenditures on their own, without any guarantee that the drug will be approved.

Kite says it has spent more than \$200 million on research and development, including running larger clinical trials than those conducted by the cancer institute, and recently spent about \$30 million to build a factory that will be able to make treatments for up to 5,000 patients a year.

Setting the price of the drug, Dr. Rosenberg said, “is for the marketplace.”

A Public-Private Partnership

Like many business deals, this one began with a personal relationship — in this case between Dr. Rosenberg and Dr. Belldgrun.

After finishing medical school in his native Israel, performing surgery in helicopters for the Israeli armed forces, and completing residency at Brigham & Women’s Hospital, Dr. Belldgrun became a research fellow for Dr. Rosenberg at the N.C.I. It was 1985, and Dr. Belldgrun was put to work on a new project of Dr. Rosenberg’s — extracting tumor-fighting immune cells from cancer patients, multiplying them in the laboratory, and putting them back in.

“He was one of the more outstanding fellows to come through,” said Dr. Rosenberg, 76, who is widely considered a cancer research luminary.

Continue reading the main story

Photo

<image004.jpg>

Dr. Belldgrun, center, at the Nasdaq stock exchange, where Kite Pharma is listed. The company was founded in 2009 and went public in 2014. Credit Nasdaq, 2016

When the fellowship ended in 1988, Dr. Belldgrun became a prominent surgeon at the University of California, Los Angeles, but the two men stayed in touch. Eventually, Dr. Belldgrun, 67, got the entrepreneurial bug. He co-founded a biotech company, Agensys, which was acquired by a bigger company for more than \$500 million. He was also involved with Cougar Biotechnology, which developed the prostate cancer drug Zytiga and was acquired by Johnson & Johnson for \$1 billion in May 2009. A month later, Dr. Belldgrun formed Kite with a group of colleagues and investors to pursue cancer immunotherapy. That same month, a Florida marine contractor named Eric Karlson, whose non-Hodgkin's lymphoma was advancing despite four prior treatments, became the first patient treated by Dr. Rosenberg with what would eventually become KTE-C19. The treatment entailed removing some of Mr. Karlson's immune system T cells from his blood, genetically engineering them to recognize and fight his cancer, multiplying the T cells to huge numbers in the laboratory and transferring them back into his body. After two such treatments, Mr. Karlson remains alive and cancer-free eight years later.

Kite initially thought it would pursue an approach to immunotherapy known as cancer vaccines, but in 2010, Dr. Belldgrun visited Dr. Rosenberg and was shown the X-rays of Mr. Karlson and of a second patient.

Dr. Belldgrun was bowled over. "I had no doubt that this is going to be a drug and, more than that, it will become a platform for multiple products," he recalled. "We never looked back."

Over the next two years, the National Cancer Institute worked out a deal with Kite that was signed in 2012. It was the first of eight contracts between the government and the company that generally take two forms.

In one type of contract, Kite licenses patented inventions and agrees to pay the government royalties, roughly 5 percent of sales of any commercial product arising from a particular patent. However, there is no such license specifically for KTE-C19 because the underlying treatment was not patented by the N.C.I., so royalties will be minimal.

Officials say the agency did not apply for a patent because the treatment was similar to what others had been developing. Also, at the time the treatment was first created, in 2007, immunotherapy was considered to have dim commercial prospects.

"Back then, we didn't even think about commercial aspects," said Dr. James N. Kochenderfer, a scientist at the agency who designed the treatment when working in Dr. Rosenberg's group.

Under the second type of contract, known as a cooperative research and development agreement, Kite provides money to the N.C.I. to support research. Kite is now paying \$3 million a year to Dr. Rosenberg's lab and has provided \$7.5 million to it in total since 2012. Based on its regulatory filings, Kite is paying \$7.8 million a year for research agreements and licenses in total, with at least \$4 million of that going to the cancer institute and the rest to academic or corporate partners.

The taxpayer has invested, too. Dr. Rosenberg estimated that the government has spent roughly \$10 million over the years on what has become KTE-C19. He said

Kite's \$3 million a year is about equal to the taxpayer funding in that area and has helped speed research.

These days, researchers from Kite and the cancer institute, typically including Dr. Rosenberg and Dr. Belldgrun, confer by conference call every other Thursday for 90 minutes. Kite employees have spent long periods at the N.C.I., learning how to manufacture the therapy and how to treat patients in advance with chemotherapy.

"We shouldn't underestimate the value and the importance of N.I.H., not only to Kite but to the whole field of engineered T-cell therapy," Dr. Belldgrun said.

When Kite signed its first deal with the cancer agency, he said, it "tapped into six years of monumental work that they had done."

Some immunotherapy competitors marvel at the company's coup in tapping into the agency's expertise. "They got 20 years of research all together in one scoop," said Dr. Carlos Paya, chief executive of Immune Design, which is pursuing a different approach.

But government officials say few, if any, other companies were interested in the technology at the time Dr. Belldgrun came calling. Dr. Rosenberg said that before Kite, a few companies, including Johnson & Johnson, had looked at an earlier version of his technology but were wary because treatment involved processing each patient's cells.

Government-developed technology available to be licensed to companies is posted on the website of the National Institutes of Health. And when the agency intends to grant a license to a particular company, it publishes that in the Federal Register, inviting public comment and possible competing offers. Both steps were taken in the case of Kite, officials said.

Kite did not get everything the cancer institute has developed in the field. Some other companies, including Opus Bio and Bluebird Bio, got rights to some products, in part because the companies had special expertise that the agency's researchers desired. But Kite seems to have gotten the balance of them and N.C.I. technology accounts for the majority of its pipeline of possible products, though the company is diversifying.

Photo

<image005.jpg>

A slide that Kite Pharma used in presentations to potential investors pointed out the company's relationship with Dr. Rosenberg.

Dr. Rosenberg professes no interest in the business side of the Kite relationship. He does not own stock in any company, even Kite, though he could get up to \$150,000 a year in patent royalties if some of Kite's efforts pay off.

Dr. Belldgrun, in contrast to his mentor, has commercial flair. He is known for his sharp business suits, lives in the Bel-Air neighborhood of Los Angeles, and seems as comfortable on Wall Street or in high society as in the operating room.

Kite's relationship with the N.C.I. is an important part of its appeal to investors. In some presentations, Dr. Belldgrun has shown a photograph of himself with Dr. Rosenberg in their younger days. And he persuaded Dr. Rosenberg to speak at Kite's first big meeting for investors in June 2015, the only time he has ever spoken to Wall Street.

In emails obtained through a Freedom of Information Act request by Knowledge Ecology International, Dr. Belldgrun praised Dr. Rosenberg's talk and sent him copies of investment reports from the conference written by Wall Street analysts. "Thank you for making the effort to come to NY," Dr. Belldgrun wrote. "I heard only raving reviews about your presence and presentation."

A 'Reasonable' Question

The reliance of private companies on government-funded research goes well beyond obvious cases like Kite. In many instances, companies work with universities or medical centers that, in turn, have been funded from the \$32 billion annual budget of the National Institutes of Health.

Kite's two main competitors, Novartis and Juno Therapeutics, for instance, derived similar immunotherapy treatments largely from academic institutions, developed at least in part with government funding. Novartis has a relationship with the University of Pennsylvania, and Juno with the Memorial Sloan Kettering Cancer Center, the Fred Hutchinson Cancer Research Center and Seattle Children's Hospital.

"For the most important drugs you'll see some public-sector involvement," said Bhaven Sampat, an associate professor of health policy and management at Columbia University. He was one author of a study that found that 9 percent of all drugs approved between 1988 and 2005 were based directly on a patent held by the public sector. But 47.8 percent of the drugs relied at least indirectly on some federally funded research.

Continue reading the main story

Photo

<image006.jpg>

Eric Karlson at his home on Marco Island, Fla., this month. Mr. Karlson's non-Hodgkin's lymphoma was successfully treated by Dr. Rosenberg with what would eventually become KTE-C19. Credit Scott McIntyre for The New York Times

The figures were higher for more medically important drugs: 17.4 percent had a direct public-sector patent, while 64.5 percent had at least an indirect public-sector influence.

These figures are up sharply from before the 1980s. Such partnerships and licensing deals were encouraged by the 1980 Bayh-Dole and Stevenson-Wydler Acts, and the 1986 Federal Technology Transfer Act. The laws are credited with jump-starting the biotechnology industry.

But from the beginning, some people questioned whether taxpayers were getting a bad deal.

Perhaps the best-known drug developed from a cooperative research and development agreement — the cancer drug Taxol — was the subject of several congressional hearings in the early 1990s that investigated whether the drug's maker, Bristol-Myers Squibb, charged too much and whether the government recouped enough of its investment. In the end, the pricing was left unchanged. The N.I.H. argues that if it imposes pricing restrictions, it won't get partners. In fact, in 1995, it struck from its negotiating tactics a goal that prices be "reasonable."

"Companies will not take technologies from us if we say the government will decide in the future what the price will be," said Mark Rohrbaugh, who ran the technology transfer office at the institutes from 2001 to 2013 and is now an adviser to the agency. After the "reasonable price" clause was struck, he said, there was a threefold increase in partnership deals.

The N.I.H. can collect royalties from successful products to help offset the costs of the research, but so far these royalties have been small, amounting to an estimated \$135 million in the last fiscal year from 870 licenses, with the bulk of the money coming from a small number of drugs.

"We're not preoccupied with financial value," Dr. Rohrbaugh said. "Our mission is treatment of people and improving public health."

In that regard, the government's bet on a small company like Kite, which might have seemed risky, appears to be paying off so far. Dr. Belldegrün has largely delivered on promises to raise money, assemble an experienced staff, build the factory, conduct clinical trials and begin to apply for regulatory approval. Once considered the underdog to Novartis and Juno, Kite might be the first reach the market.

Photo

<image007.jpg>

Scans of Mr. Karlson's body before and after his treatment. In the cross-sections on the left, the arrows point to signs of lymphoma in areas such as his armpits, chest, spleen and pelvis. Credit National Cancer Institute

Academic centers and companies often drive harder bargains in licensing technology. In some cases, academic centers own a stake in a company they license technology to, allowing them to reap a financial windfall if the company does well. Both the Hutchinson cancer center and Sloan Kettering have owned stock in Juno and are entitled to substantial payments — up to \$350 million and \$150 million — if Juno's stock reaches certain levels.

The N.I.H. does not take equity positions in companies to avoid an appearance of a conflict of interest. So to critics of the government deals, drug prices are crucial to understanding taxpayer value. After all, they ask, is a drug truly widely available — which is what the government says is its measure of success — if it costs too much for some people?

Rachel Sachs, an associate law professor at Washington University in St. Louis and expert in innovation policy, said the government had every right to seek price concessions. She noted that the government, through Medicare and Medicaid, was effectively buying its inventions back from itself. "The public is paying for the research and to the extent that many people, if not most, will pay through public insurance, we're paying again," she said.

Hillary Clinton, in her campaign for president, promised to set new rules for federal support of research so that Americans "get the value they deserve" for the money taxpayers spend in supporting research. It is not clear how President-elect Donald J. Trump will approach these issues; he has said he favors reducing health care costs, but Republicans, who control Congress, too, have opposed government involvement in price setting.

One mechanism to control pricing already exists. It is called march-in rights, and it lets the N.I.H. take back control of a patent on an invention made with federal funding if the drug is not being made available to the public on reasonable terms. The tool has gone unused.

Earlier this year, Knowledge Ecology International and another advocacy group, the Union for Affordable Cancer Treatment, petitioned the agency to exercise march-in rights on Xtandi, a prostate cancer drug that was developed by federally funded researchers at U.C.L.A. It said the price in the United States of about \$129,000 a year, two to four times that in other developed countries, meant the drug was not reasonably available. The effort was supported by other public interest groups and some Democratic members of Congress.

U.C.L.A. made more than \$500 million by selling its royalty rights to the drug. But the N.I.H. declined to exercise its march-in rights on Xtandi, arguing that it was not qualified to judge whether a drug's price is reasonable and that a high price does not mean a drug is not being made available to the public.

"N.I.H. has made it clear that its job is not to decide prices of drugs, period," Dr. Rohrbaugh said

Kite says it has not decided what to charge for KTE-C19, but Dr. Belldegrun hinted that Kite's therapy might be relatively expensive because ideally it would be a single treatment that would cure the patient, not a drug that would have to be taken continuously. He added that Kite would take steps to make sure that everyone who needed the drug could get it.

Meantime, the relationship between Kite and the National Cancer Institute is expanding to develop treatments for other cancers, including one technique Dr. Rosenberg thinks could be used to attack solid tumors like colon, breast and lung cancer.

"The potential for broad applicability is huge," he said.

That could mean many lives saved and maybe more billion-dollar drugs for Kite and its investors, with the American taxpayer right in the middle of the deal.

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The new temporary contact for FOIA seems to be Marin Allen.

From: Kassilke, Deborah (NIH/OD) [E]
Sent: Thursday, January 12, 2017 12:06 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Subject: Re:
Importance: High

Hi Mark –

In the past 10 or so business days we have received 3 requests from KEI/LOVE. I've captured them in the attached word doc.

b5

I will find out who in FOIA to work with given Susan C is gone, but would like your thoughts.

Deb

*Deborah Kassilke
Director, Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852
E-Mail: Deborah.Kassilke@nih.gov
Phone: 301-435-5294
Cell: 240-701-8159*

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 1/27/2017 3:15:08 PM
To: Mowatt, Michael (NIH/NIAID) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIAID/cn=MMOWATT]
Subject: Fwd: [Ip-health] Army extends comment period on Zika vaccine patent license to Sanofi, to March 10.

Sent from my iPhone

Begin forwarded message:

From: "Lambert, Richard (NIH/NIAID) [C]" <lambertr@niaid.nih.gov>
Date: January 27, 2017 at 9:11:24 AM EST
To: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Subject: **FW: [Ip-health] Army extends comment period on Zika vaccine patent license to Sanofi, to March 10.**

Hi, Mark, I assume you saw this.
Dick

Richard A. Lambert
Contractor
National Institute of Allergy and Infectious Diseases
National Institutes of Health
U.S. Department of Health and Human Services
5601 Fishers Lane, Rm. 2G47, MSC 9804
Bethesda, MD 20892-9804
(Courier: Rockville, MD. 20852)
301.496.2644 main officeline
240.627.3706 direct line
FAX 240.627.3117
lambertr@niaid.nih.gov

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-----Original Message-----

From: Jamie Love [<mailto:james.love@keionline.org>]
Sent: Friday, January 27, 2017 3:50 AM
To: Ip-health <ip-health@lists.keionline.org>
Subject: [Ip-health] Army extends comment period on Zika vaccine patent license to Sanofi, to March 10.

Thanks to all of the persons who have worked on this, the US Army has now extended the comment period on the Sanofi license for the Zika vaccine patents to March 10. This is the second extension of time for comment. To put into perspective, we have never been able to get a comment extension by the NIH on its exclusive licenses.

REL0000024768

Members of Congress have been pressing the Army to provide information about the proposed license, including the federal funding of the vaccine development, and Sanofi's actual contributions to the R&D funding, which appear to be net zero, given the grants Sanofi is receiving for this.

Dr. Diane Singhroy is researching the manufacturing issues relating to the vaccine, which is based upon an earlier vaccine developed in 2009, using the same platform.

A pretty interesting account of the extensive role of HHS and the Army in the development and funding of the vaccine is available in this NIH press release from November 7, 2016.

<https://www.nih.gov/news-events/news-releases/testing-investigational-inactivated-zika-vaccine-humans-begins>

"The experimental ZPIV vaccine is based on the same technology WRAIR used in 2009 to successfully develop a vaccine for another flavivirus called Japanese encephalitis. . . . WRAIR, NIAID and the Biomedical Advanced Research and Development Authority (BARDA) part of the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) have established a joint Research Collaboration Agreement to support the development of this vaccine."

.... and the press release details the various trials the US government is funding, and that "BARDA is funding the advanced development of the ZPIV vaccine candidate through a six-year contract with Sanofi Pasteur, which established a collaborative research and development agreement with WRAIR to accelerate further development of the vaccine."

People might want to reflect on the future price negotiations over this vaccine, when what is stake is a vaccine to prevent a baby from being born with a small head and brain damage. What's that worth these days? If Army grants the exclusive license, and the vaccine works, we will find out what Sanofi thinks people will pay.

What we also don't know yet is what rights the NIH or the Army are giving in the test data to Sanofi, the French company, for the trials the US taxpayer is funding.

Here is the federal register notice.

Jamie

<https://www.federalregister.gov/documents/2017/01/27/2017-01851/intent-to-grant-an-exclusive-license-of-us-government-owned-patents>

The Federal Register

Notice: Intent To Grant an Exclusive License of U.S. Government-Owned Patents A Notice by the Army Department on 01/27/2017

DOCUMENT DETAILS

Publication Date: 01/27/2017

Agencies: Department of the Army

Document Type: Notice

Document Citation: 82 FR 8611
Page: 8611 (1 page)
Document Number: 2017-01851

SUMMARY:

The comment period for the Intent to Grant an Exclusive License of U.S. Government-Owned Patents published in the Federal Register on Friday, December 9, 2016 (81 FR 89087), required comments be postmarked on or before December 24, 2016 and again on January 23, 2017. The comment period has been extended to March 10, 2017.

FOR FURTHER INFORMATION CONTACT:

Mr. Barry Datlof, Office of Research & Technology Assessment, (301) 619-0033. For patent issues, Ms. Elizabeth Arwine, Patent Attorney, (301) 619-7808, both at telefax (301) 619-5034.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2017-01851 Filed 1-26-17; 8:45 am]

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James Love. Knowledge Ecology International <http://www.keionline.org/donate.html>
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+41.76.413.6584, twitter.com/jamie_love

Ip-health mailing list

Ip-health@lists.keionline.org

http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org

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>
> Here is the federal register notice.
>
> Jamie
>
> <https://www.federalregister.gov/documents/2017/01/27/2017-01851/intent-to-grant-an-exclusive-license-of-us-government-owned-patents>
>
> The Federal Register
>
> Notice: Intent To Grant an Exclusive License of U.S. Government-Owned Patents A Notice by the Army Department on 01/27/2017
>
> DOCUMENT DETAILS
> Publication Date: 01/27/2017
> Agencies: Department of the Army
> Document Type: Notice
> Document Citation: 82 FR 8611
> Page: 8611 (1 page)
> Document Number: 2017-01851
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>
> Brenda S. Bowen,
>
> Army Federal Register Liaison Officer.
>
> [FR Doc. 2017-01851 Filed 1-26-17; 8:45 am]
>
>
> --
> James Love. Knowledge Ecology International <http://www.keionline.org/donate.html>
> KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile:
> +41.76.413.6584, twitter.com/jamie_love
>

> Ip-health mailing list
> Ip-health@lists.keionline.org
> http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 1/27/2017 1:27:38 PM
To: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: Re: Feb 24

I agree

Sent from my iPhone

On Jan 27, 2017, at 8:12 AM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:

Mark: I am unable to participate in this panel

b5

b5

Ann

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Friday, January 27, 2017 7:49 AM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: Fwd: Feb 24

Sent from my iPhone

Begin forwarded message:

From: Jamie Love <james.love@keionline.org>
Date: January 27, 2017 at 7:32:30 AM EST
To: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@od.nih.gov>
Subject: Feb 24

Mark,

Could we get anyone from the NIH to participate on panel 4 of this event on compulsory licensing on Feb 24? I am reaching out to PhRMA and the Association of University Technology Managers too. If the NIH cannot participate, I would also be grateful for suggestions of persons who might be opposed to the use of March-In rights for government funded research. We tried to get Joe Allen, but he says he expects jury duty on that day.

Jamie

<http://www.keionline.org/node/2717>

REL0000024771

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

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+41.76.413.6584, twitter.com/jamie_love

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 1/27/2017 1:28:33 PM
To: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: Re: Feb 24

I totally agree, just thought you might enjoy the opportunity

Sent from my iPhone

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<http://www.keionline.org/node/2717>

REL0000024773

--

James Love. Knowledge Ecology International

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+41.76.413.6584, twitter.com/jamie_love

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 6/16/2017 1:44:31 PM
To: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: Re: Please send a copy of the signed KEI Response

When I get it.

Sent from my iPhone

On Jun 16, 2017, at 9:37 AM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:

--

Ann M. Hammersla, J.D.
Director
Division of Extramural Inventions and Technology Resources
Office of Policy for Extramural Research Administration
Rockledge 1, Suite 310
6705 Rockledge Drive
Bethesda, Maryland 20892-7974
PHONE: 301-435-0745

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 6/16/2017 1:45:45 PM
To: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: Re: Please send a copy of the signed KEI Response

Looks like Exec Sec wants to have it formally cleared by OER and OGC

Sent from my iPhone

On Jun 16, 2017, at 9:37 AM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:

--

Ann M. Hammersla, J.D.
Director
Division of Extramural Inventions and Technology Resources
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6705 Rockledge Drive
Bethesda, Maryland 20892-7974
PHONE: 301-435-0745

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 6/15/2017 9:08:55 PM
To: Mowatt, Michael (NIH/NIAID) [E] [/O=NIH/OU=NIEXCHANGE/cn=NIAID/cn=MMOWATT]; Lambert, Richard (NIH/NIAID) [C] [/O=NIH/OU=NIEXCHANGE/cn=NIAID/cn=LAMBERTR]
Subject: Fwd: Lawmakers ask U.S. Army to hold a hearing on Zika vaccine licensing

Sent from my iPhone

Begin

Here's FiercePharma's story:

Lawmakers in hard-hit Florida want public hearing in Sanofi Zika vaccine scuffle

by [Eric Sagonowsky](#) |
Jun 15, 2017 8:00am

Having seen Zika's devastating effects reach Florida residents, a bipartisan group of lawmakers in the state is urging the Army to pump the brakes on its exclusive vaccine license to Sanofi.

In letters to acting Army Secretary Robert Speer, nine members of the House of Representatives from the state and Sen. Bill Nelson have castigated the proposed vaccine license, questioning why the partners can't include a fair pricing assurance. The House members are [requesting](#) that the license be delayed until officials can hold a public hearing on the plan.

RELATED: [Sanofi's Zika-shot pricing dust-up highlights a divide over taxpayer-backed vaccine R&D](#)

For his part, Sen. Nelson noted that more than 1,400 cases of Zika have been documented in Florida. He [wrote](#) (PDF) that a "failure to limit the vaccine's market price could make it inaccessible to thousands of Floridians who need it." Nonprofit Knowledge Ecology International (KEI) posted the letters on its website Wednesday.

The Army and reportedly Sanofi itself have rejected calls for pricing assurances on the planned license, first announced late last year. Their refusal has angered politicians and public watchdog groups who have pointed out that the vaccine was developed with funds from U.S. taxpayers.

In response to the requests, the Army said it simply can't enforce future vaccine prices. Sanofi has said that the terms of the license are still under negotiation.

KEI was among the first to protest the proposed license, kicking off a campaign that's gained a great deal of steam in recent months. Sen. Bernie Sanders wrote a New York Times op-ed [requesting](#) the Trump

administration call the deal off, and Sanofi R&D head Elias Zerhouni defended his company in the same newspaper.

RELATED: Lawmakers decry Army's planned Zika vaccine license to Sanofi

Zerhouni pointed out that Sanofi wouldn't be getting something for nothing in the deal and that the drugmaker would have to pay "significant" milestone and royalty payments if the partners are able to develop a successful vaccine. Before the Florida lawmakers wrote to protest the deal, a separate group of 11 Democrats urged against the license back in February.

On Wednesday, KEI's counsel for policy and legal affairs, Andrew Goldman, said in a written statement that the new letters "highlight the absurdity of paying for virtually all of the R&D for the vaccine, giving a French company a monopoly until 2036, and not having any conditions on the price before signing the license."

The U.S. government is also partnered with GlaxoSmithKline and Takeda on different Zika vaccine approaches, and the proposed license to Sanofi would not prohibit other companies from bringing vaccines to market and competing on price.

"Whether or not the agreement with WRAIR is exclusive or non-exclusive, the license does not prevent other companies from pursuing vaccine candidates based on alternative technologies which have the potential to be more viable than this one," a Sanofi spokesperson said on Wednesday. "There is a very strong likelihood there will be a competitive Zika vaccine marketplace with 32 Zika vaccines in early development. Many of these other companies are also receiving funding from the U.S. government."

RELATED: Sanofi executive lays out case for taxpayer funding—and exclusive licensing—on Zika vaccine R&D

Further, it's in the "public-health interest for Sanofi to price this and other vaccines in a way that will facilitate access to and usage of a preventative vaccine," she said.

The Army is set to decide on the license by the fall, according to the Miami Herald. Its press office didn't immediately respond to a request for comment on the letters.

Sanofi partnered with the U.S. Army last summer and has since won \$43 million in government funds to support the project. Another \$130 million could be awarded for future work. Army scientists originally developed the candidate. Market-watchers have predicted the Zika vaccine market could be worth \$1 billion per year or more.

On 6/14/2017 3:22 PM, Rohrbaugh, Mark (NIH/OD) [E] wrote:

FYI: <https://www.statnews.com/pharmalot/2017/06/14/lawmakers-army-zika-vaccine/>. NIH is mentioned at the end of the article.

Lawmakers ask U.S. Army to hold a hearing on Zika vaccine licensing

By ED SILVERMAN @Pharmalot
JUNE 14, 2017

A group of Florida lawmakers is urging the U.S. Army to hold a hearing on its plan to give Sanofi an exclusive license to develop a Zika virus vaccine, a move that has raised concerns the product may be priced too high for many Americans, even though it was developed with taxpayer funds.

In a June 13 [letter](#), eight U.S. House Democrats and one Republican expressed concern about the “potential for monopolistic practices that would, effectively, keep this life-saving vaccine out of reach for far too many of our constituents.” At the same time, U.S. Sen. Bill Nelson, who is also a Democrat, sent his own [letter](#) in which he urged the Army to limit the price for the vaccine.

Both missives noted that Sanofi, which is one of the world’s largest vaccine makers, has already won a \$43 million government grant and stands to receive another \$130 million to run late-stage trials. Consequently, the representatives argued that awarding an exclusive license to the company would add “insult to injury,” and they want the Army to explain how such a license is reasonable or necessary.

This the second time in recent weeks that lawmakers from a Gulf state have decried plans for an exclusive license. Last month, Louisiana Gov. John Edwards warned Acting U.S. Army Secretary Robert Speer that if the mosquito-borne virus spreads, the possibility of monopoly pricing “could cripple state budgets and threaten public health.”

The letters may ratchet up the pressure on the Army to change course amid cries from still other lawmakers and consumer advocates to demand that Sanofi agree to some kind of pricing agreement as part of any licensing deal. As we reported recently, however, the company in April [rejected such a request](#) from the Army, although overall licensing talks are still under way.

We asked the Army if a hearing will be scheduled and we will update you accordingly.

The episode highlights a growing debate about the extent to which drug makers should be allowed to benefit from products that are developed — at least in part — with taxpayer funds. In this instance, the lawmakers and consumer advocates are concerned over speculation that, if the virus spread quickly, Sanofi will have a lock on a potentially lucrative market.

One group, Knowledge Ecology International, argued Sanofi cannot be trusted and pointed to pricing for its Aubagio multiple sclerosis drug. Americans using a coupon can pay about \$6,100 for a month's supply — which is seven times more than patients pay in France and at least four times the price in the UK, Ireland, and Australia. Sanofi countered that prices vary due to circumstances in each country.

The advocacy group has also made a point of citing federal law indicating exclusive licensing should be made only to serve a public benefit. But in a recent [letter](#) to U.S. Sen. Bernie Sanders, Robert Speer, noted that only Sanofi was “willing to license” this specific discovery, prompting concern that the Army is unwilling to push the company about pricing over fears it may walk away.

For its part, Sanofi has said that a price has not yet been set, but one executive maintained that royalties would be paid. Meanwhile, in a May 22 letter to a Congressional subcommittee, another Sanofi executive insisted the company is not pursuing the project based on a “commercial return” and intends to price the vaccine in order to “facilitate access” in the interest of public health.

Moreover, Adam Gluck, who heads U.S. government relations at Sanofi, noted that the company delayed other R&D programs to speed development of the vaccine out of a “sense of corporate responsibility” to address a potential public health crisis. But he also warned that, “given the high-risk nature of vaccine development unpredictability for diseases like Zika, if the U.S. government changes its historic approach to licensing terms, it could undermine the intent of these types of collaborations.”

His language raised debate over whether the federal government should reinstate language in research agreements that contain “reasonable pricing.” This requirement was removed by the U.S. National Institutes of Health in 1995 over concerns that such clauses would be seen by industry as a “restraint” on new product development.

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 6/21/2017 7:06:35 PM
To: Gottesman, Michael (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=GottesmM]; Owens, Roland (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIDDK/cn=ROLANDO]; Garcia-Perez, Arlyn (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=GarciaA]; Dearolf, Charles (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=CSR/cn=DEAROLF]; Colbert, Melissa (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=colbertmc]; McBurney, Margaret (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=cc/cn=mmcurney]; Wanjek, Christopher (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=wanjekc]
Subject: Fwd: Response to CRISPR patented inventions letter
Attachments: 1 CRISPR-SecPrice-6Jan2017.pdf; ATT00001.htm

NIH declines to develop new policies for CRISPR patent licensing. Existing policies are sufficient, and NIH will monitor use and development in case Access problems develop.

Note:

b5

Sent from my iPhone

Begin forwarded message:

From: "Jorgenson, Lyric (NIH/OD) [E]" <jorgensonla@od.nih.gov>
To: "james.love@keionline.org" <james.love@keionline.org>, "diane.singhroy@keionline.org" <diane.singhroy@keionline.org>, "Andrews.goldman@keionline.org" <Andrews.goldman@keionline.org>
Cc: "Wolinetz, Carrie (NIH/OD) [E]" <carrie.wolinetz@nih.gov>
Subject: Response to CRISPR patented inventions letter

Dear Mr. Love, Ms. Singhroy and Mr. Goldman,

Please find below a response from Dr. Carrie Wolinetz, Acting Chief of Staff and Associate Director for Science Policy at the NIH, to your letter to Drs. Price and Collins requesting the HHS develop a policy on the licensing of federally-funded CRISPR patented inventions.

Lyric Jorgenson, PhD
Deputy Director, Office of Science Policy
National Institutes of Health
jorgensonla@od.nih.gov
301.496.6837

Dear Mr. Love, Ms. Singhroy and Mr. Goldman:

Thank you for your June 6, 2017 correspondence to Dr. Thomas Price, Secretary of Health and Human Services (HHS), and Dr. Francis S. Collins, Director of the National Institutes of Health (NIH) requesting the HHS develop a policy on the licensing of federally-funded CRISPR patented inventions. The NIH reviewed the information you provided pertaining to the CRISPR

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technology as well as other information that is publicly available. You raise important issues regarding the licensing of NIH-funded patented technologies that have both research and clinical uses.

Among the benefits derived from NIH-conducted and supported biomedical research are effective and broadly accessible new healthcare treatments and services that benefit the public. Practical realization of these benefits depends on the ability and willingness of private sector partners to develop and commercialize new technologies arising from NIH-funded research. When NIH funding leads to a patented invention, NIH policies provide guidance to institutions licensing the patents to facilitate on-going scientific research with the patented technology and, at the same time, provide appropriate incentives for commercial development.

The relevant NIH policies are stated in *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources*, December 23, 1999; https://grants.nih.gov/grants/intell-property_64FR72090.pdf. The principles are to: (1) ensure academic freedom and publication; (2) ensure appropriate implementation of the Bayh-Dole Act, which is incorporated into NIH's funding agreements; (3) minimize administrative impediments to academic research; and; (4) ensure dissemination of resources that are developed with NIH funds. NIH guidelines and policies, which apply to all technologies including CRISPR, encourage patent owners to grant non-exclusive licenses to technologies developed with NIH funds whenever possible. In those cases where exclusive licensing is required to encourage development by private partners, exclusive licenses should be appropriately tailored to ensure expeditious development of as many aspects of the technology as possible and to ensure development of the technology in all research fields and product areas. NIH policies state that specific indications, fields of use, and territories should be limited to be commensurate with the abilities and commitment of licensees to expeditiously bring a technology to market, and further recites that no license program should prohibit continued research and innovation.

CRISPR-CAS9 technology is a foundational and broadly applicable platform technology that enables researchers to engage in scientific inquiry and companies to develop products and services that could benefit a broad range of patients. While there are ongoing legal proceedings regarding these patents and patent applications, the Broad Institute is a primary owner and licensor of patents on CRISPR-CAS9. According to the Broad Institute's public statements found at <https://www.broadinstitute.org/partnerships/office-strategic-alliances-and-partnering/information-about-licensing-crispr-genome-ed>, Broad, the Massachusetts Institute of Technology, and Harvard University (co-owners of the patents) have developed a licensing program to provide for broad access of the CRISPR-CAS9 technology to researchers and commercial developers. In summary, Broad's and its partners' licensing program for the CRISPR-CAS9 states: (1) tools, knowledge, methods and other intellectual property for genome-editing will be freely available to the academic and non-profit community; (2) non-exclusive licenses will be granted to companies to use CRISPR-CAS9 in their commercial research and to companies who will develop and sell research tools and reagents for genome editing; and, (3) for commercial development of human therapeutics that will require a significant level of investment, exclusive license requests for specific gene targets not otherwise under development will be considered. Broad reports that, since February 2013, more than 37,000 plasmids and reagents have been provided to more than 2,000 institutions across 59 countries.

Broad further explains that the technology will be licensed under a model that apparently has as its objective the efficient distribution of defined exclusive fields of use to commercial partners. Under this model, Broad, Harvard, and MIT have licensed their CRISPR technology to

a primary licensee, Editas Medicine, Inc. (Editas) to exclusively use the technology on targets of its choosing for the development of genomic medicines. However, Broad retains some controls over sublicensing decisions by Editas to allow for the breadth of the technology to be exploited commercially. After an initial period, other companies may apply for commercial licenses to certain CRISPR patents for use against genes of interest not being actively pursued by Editas.

While we have not received any inquiries or complaints about lack of access to the CRISPR-CAS9 technology for research or commercial development from those who are in a position to use the technology, we continue to monitor access and use of the CRISPR technology that was funded by NIH with respect to public access and compliance with NIH principles and policies. At this time, we do not believe that a new NIH policy to address the licensing of CRISPR patented technology is necessary.

Sincerely,

Carrie D. Wolinetz, Ph.D.
Acting Chief of Staff and Associate Director for
Science Policy
National Institutes of Health

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/OD/CN=ROHRBAUM]
Sent: 2/16/2016 10:32:36 PM
To: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIH/OD/CN=HAMMERSLAA]
CC: Berkley, Dale (NIH/OD) [E] [/O=NIH/OU=NIH/OD/CN=BERKLEYD]; Hruszkewycz, Andrew (NIH/NCI) [E] [/O=NIH/OU=NIH/OD/CN=HRUSZKEA]; Muroff, Julie (NIH/OD) [E] [/O=NIH/OU=NIH/OD/CN=MUROFFJ]
Subject: Re: KEI 01/14/2014 Bayh-Dole March-In Request

4 works for me. I will check with OTT

Sent from my iPhone

On Feb 16, 2016, at 1:10 PM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:

It appears that 2/23 at 1:00 does not work for everyone. How about 4:00 on 2/23rd? Can you make it then?

Other NIH march-in decisions: Were on the OTT website and it appears this afternoon they have been taken down. I will see what I can do to find a current link to them. Mark – do you know where OTT included these decisions as well as other NIH specific decisions?

Links to:

Knowledge Ecology International : <http://www.keionline.org/>
Information on KEI's website regarding this march-in request: <http://www.keionline.org/node/2412>

Ann

From: Hammersla, Ann (NIH/OD) [E]
Sent: Tuesday, February 16, 2016 1:30 PM
To: Hruszkewycz, Andrew (NIH/NCI) [E]; Rohrbaugh, Mark (NIH/OD) [E]; Berkley, Dale (NIH/OD) [E]; Muroff, Julie (NIH/OD) [E]
Cc: Bulls, Michelle G. (NIH/OD) [E]; Helfer, Jacqueline (NIH/OD) [C]; Cooper, Scott (NIH/OD) [E]
Subject: KEI 01/14/2014 Bayh-Dole March-In Request

Good Morning Andrew, Mark, Dale and Julie:

I am writing to ask each of you to assist OPERA/DETR in reviewing and responding to the attached march-in request and the request to use the government's royalty-free license from Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (ACT). I would like to arrange for a call of all of us on February 23 at 1:30. Are you available?

The KEI request is to use the government's rights on 3 inventions that were jointly supported by NIH and the Army. The inventions and subsequent patents are used for the prostate cancer drug (enzalutamide) marketed under the brand name of Xtandi by Japan-based Astellas Pharma. All 3 patents identify CA 092131 as funding the underlying research for these inventions and patents.

I have attached a summary of march-in and the government's royalty-free license. I have been in contact with the Army and it has requested to participate in our discussions which we can discuss when we meet.

The summary of KEI's request is:

"Xtandi is an expensive drug everywhere, indeed so expensive that access is extremely limited in many countries. But, based upon research, the prices in the United States are far higher than any other country in the world, despite the fact that the critical research benefited from U.S. taxpayer funded grants from the NIH and DOD."

Mark – could you please send to everyone NIH's recent response or draft response to the Congressional inquiry about the use of NIH's march-in authority and the pricing of the drugs?

OGC: I am not sure if one or both of you will be participating – just let me know.

Please let me know if you are available on 2/23rd at 1:30.

Ann

--

Ann M. Hammersla, J.D.
Director
Division of Extramural Inventions and Technology Resources
Office of Policy for Extramural Research Administration
Director, Division of Policy, Office of Technology Transfer
Rockledge 1, Suite 310
6705 Rockledge Drive
Bethesda, Maryland 20892-7974
PHONE: 301-451-4235

From: Rohrbach, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/OD/CN=OD/CN=ROHRBAUM]
Sent: 6/21/2017 7:01:01 PM
To: Rodriguez, Richard (NIH/NCI) [E] [/O=NIH/OU=EXTernal (FYDIBOHF25SPDLT)/cn=Recipients/cn=5c43750192ca4e0e890422519477dd41]; Rucker, Susan (NIH/NCI) [E] [/O=NIH/OU=EXTernal (FYDIBOHF25SPDLT)/cn=Recipients/cn=ac50fd0447444c2e9666d65287a9af2f]
Subject: Fwd: Response to CRISPR patented inventions letter
Attachments: 1 CRISPR-SecPrice-6Jan2017.pdf; ATT00001.htm

Sent from my iPhone

Begin forwarded message:

From: "Jorgenson, Lyric (NIH/OD) [E]" <jorgensonla@od.nih.gov>
To: "james.love@keionline.org" <james.love@keionline.org>, "diane.singhroy@keionline.org" <diane.singhroy@keionline.org>, "Andrews.goldman@keionline.org" <Andrews.goldman@keionline.org>
Cc: "Wolinetz, Carrie (NIH/OD) [E]" <carrie.wolinetz@nih.gov>
Subject: Response to CRISPR patented inventions letter

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Deputy Director, Office of Science Policy
National Institutes of Health
jorgensonla@od.nih.gov
301.496.6837

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Among the benefits derived from NIH-conducted and supported biomedical research are effective and broadly accessible new healthcare treatments and services that benefit the

REL0000024788

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Acting Chief of Staff and Associate Director for
Science Policy
National Institutes of Health

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 6/23/2017 1:36:50 AM
To: Bayha, Ryan (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ORS/cn=BAYHAR]
Subject: Fwd: Response to CRISPR patented inventions letter
Attachments: 1 CRISPR-SecPrice-6Jan2017.pdf; ATT00001.htm

Sent from my iPhone

Begin forwarded message:

From: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
To: "Hammersla, Ann (NIH/OD) [E]" <hammerslaa@mail.nih.gov>, "Berkley, Dale (NIH/OD) [E]" <BerkleyD@OD.NIH.GOV>, "Culhane, Ned (NIH/OD) [E]" <culhance@mail.nih.gov>, "Berkson, Laura (NIH/OD) [E]" <laura.berkson@nih.gov>, "Myles, Renate (NIH/OD) [E]" <mylesr@od.nih.gov>
Subject: FW: Response to CRISPR patented inventions letter

From: Jorgenson, Lyric (NIH/OD) [E]
Sent: Wednesday, June 21, 2017 2:39 PM
To: james.love@keionline.org; diane.singhroy@keionline.org; Andrews.goldman@keionline.org
Cc: Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>
Subject: Response to CRISPR patented inventions letter

Dear Mr. Love, Ms. Singhroy and Mr. Goldman,

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National Institutes of Health
jorgensonla@od.nih.gov
301.496.6837

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REL0000024790

technology as well as other information that is publicly available. You raise important issues regarding the licensing of NIH-funded patented technologies that have both research and clinical uses.

Among the benefits derived from NIH-conducted and supported biomedical research are effective and broadly accessible new healthcare treatments and services that benefit the public. Practical realization of these benefits depends on the ability and willingness of private sector partners to develop and commercialize new technologies arising from NIH-funded research. When NIH funding leads to a patented invention, NIH policies provide guidance to institutions licensing the patents to facilitate on-going scientific research with the patented technology and, at the same time, provide appropriate incentives for commercial development.

The relevant NIH policies are stated in *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources*, December 23, 1999; https://grants.nih.gov/grants/intell-property_64FR72090.pdf. The principles are to: (1) ensure academic freedom and publication; (2) ensure appropriate implementation of the Bayh-Dole Act, which is incorporated into NIH's funding agreements; (3) minimize administrative impediments to academic research; and; (4) ensure dissemination of resources that are developed with NIH funds. NIH guidelines and policies, which apply to all technologies including CRISPR, encourage patent owners to grant non-exclusive licenses to technologies developed with NIH funds whenever possible. In those cases where exclusive licensing is required to encourage development by private partners, exclusive licenses should be appropriately tailored to ensure expeditious development of as many aspects of the technology as possible and to ensure development of the technology in all research fields and product areas. NIH policies state that specific indications, fields of use, and territories should be limited to be commensurate with the abilities and commitment of licensees to expeditiously bring a technology to market, and further recites that no license program should prohibit continued research and innovation.

CRISPR-CAS9 technology is a foundational and broadly applicable platform technology that enables researchers to engage in scientific inquiry and companies to develop products and services that could benefit a broad range of patients. While there are ongoing legal proceedings regarding these patents and patent applications, the Broad Institute is a primary owner and licensor of patents on CRISPR-CAS9. According to the Broad Institute's public statements found at <https://www.broadinstitute.org/partnerships/office-strategic-alliances-and-partnering/information-about-licensing-crispr-genome-ed>, Broad, the Massachusetts Institute of Technology, and Harvard University (co-owners of the patents) have developed a licensing program to provide for broad access of the CRISPR-CAS9 technology to researchers and commercial developers. In summary, Broad's and its partners' licensing program for the CRISPR-CAS9 states: (1) tools, knowledge, methods and other intellectual property for genome-editing will be freely available to the academic and non-profit community; (2) non-exclusive licenses will be granted to companies to use CRISPR-CAS9 in their commercial research and to companies who will develop and sell research tools and reagents for genome editing; and, (3) for commercial development of human therapeutics that will require a significant level of investment, exclusive license requests for specific gene targets not otherwise under development will be considered. Broad reports that, since February 2013, more than 37,000 plasmids and reagents have been provided to more than 2,000 institutions across 59 countries.

Broad further explains that the technology will be licensed under a model that apparently has as its objective the efficient distribution of defined exclusive fields of use to commercial partners. Under this model, Broad, Harvard, and MIT have licensed their CRISPR technology to

a primary licensee, Editas Medicine, Inc. (Editas) to exclusively use the technology on targets of its choosing for the development of genomic medicines. However, Broad retains some controls over sublicensing decisions by Editas to allow for the breadth of the technology to be exploited commercially. After an initial period, other companies may apply for commercial licenses to certain CRISPR patents for use against genes of interest not being actively pursued by Editas.

While we have not received any inquiries or complaints about lack of access to the CRISPR-CAS9 technology for research or commercial development from those who are in a position to use the technology, we continue to monitor access and use of the CRISPR technology that was funded by NIH with respect to public access and compliance with NIH principles and policies. At this time, we do not believe that a new NIH policy to address the licensing of CRISPR patented technology is necessary.

Sincerely,

Carrie D. Wolinetz, Ph.D.
Acting Chief of Staff and Associate Director for
Science Policy
National Institutes of Health

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 1/13/2016 11:36:57 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wolinetzc9a]; Hudson, Kathy (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Hudsonkl]
Subject: Fwd: March-In - Phone Call from James Love

note that Jamie Love has told OTT that he is submitting a March-in request for a "prostate drug" to NIH (FC). We had agreed in the TT reorg that OER will have the lead and coordinate with OSP and the funding IC to consider March-in requests.

Mark

Sent from my iPhone

Begin forwarded message:

From: "Rogers, Karen (NIH/OD) [E]" <RogersK@od.nih.gov>
Date: January 13, 2016 at 5:43:53 PM EST
To: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Subject: March-In - Phone Call from James Love

Hi Mark – Wanted to let you know that I received a call from a “old friend” of yours. James Love called to let me know that he is sending in a March-In Request to Dr. Collins for a Prostate Cancer Drug. He asked if he should send you a copy directly and I let him know that sending it to Dr. Collins was enough. It would be sent to the appropriate NIH offices for reply. When you get a chance, would you mind giving me a “lesson” on the March-In review process and how they have been handled in the past? Regards, Karen

*Karen L. Rogers
Acting Director, Office of Technology Transfer
Senior Royalties Administrator*

*Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852
E-Mail: RogersK@nih.gov
Phone: 301-435-4359
Fax: 301-402-8678*

SENSITIVE/CONFIDENTIAL INFORMATION

The attached information may be confidential. It is intended only for the addressee(s) identified above. If you are not the addressee(s), or an employee or agent of the addressee(s), please note that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this e-mail in error, please destroy the document and notify the sender of the error. Thank you.

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 1/13/2016 11:39:47 PM
To: Rogers, Karen (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=GarrettK]
CC: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: Re: March-In - Phone Call from James Love

We'll make up for it somehow. 😊

Sent from my iPhone

On Jan 13, 2016, at 6:37 PM, Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov> wrote:

Best news I've heard in a long time. Thanks Mark

Sent from my iPhone

On Jan 13, 2016, at 6:32 PM, Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV> wrote:

Thanks. He is a better friend of Ann's.

Since March-in is for extramural inventions, OER has the lead and will coordinate with me in OSP and the funding IC. OTT is no longer involved.

Sent from my iPhone

On Jan 13, 2016, at 5:43 PM, Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov> wrote:

Hi Mark – Wanted to let you know that I received a call from a “old friend” of yours. James Love called to let me know that he is sending in a March-In Request to Dr. Collins for a Prostate Cancer Drug. He asked if he should send you a copy directly and I let him know that sending it to Dr. Collins was enough. It would be sent to the appropriate NIH offices for reply. When you get a chance, would you mind giving me a “lesson” on the March-In review process and how they have been handled in the past? Regards, Karen

*Karen L. Rogers
Acting Director, Office of Technology Transfer
Senior Royalties Administrator*

*Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852
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Fax: 301-402-8678*

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dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this e-mail in error, please destroy the document and notify the sender of the error. Thank you.

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 1/14/2016 1:10:36 PM
To: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: Re: March-In - Phone Call from James Love

I am the lead in OSP, it will be cleared by OER and I will send you a draft today for comments before it goes to Exec sec tomorrow

Sent from my iPhone

On Jan 14, 2016, at 6:47 AM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:

Good Morning Mark: Thanks for the heads-up on this possible march-in request. Who is handling the march-in response to Congress? Both of these reviews and responses need to be similar.

Ann

From: Rogers, Karen (NIH/OD) [E]
Sent: Wednesday, January 13, 2016 6:38 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: Re: March-In - Phone Call from James Love

Best news I've heard in a long time. Thanks Mark

Sent from my iPhone

On Jan 13, 2016, at 6:32 PM, Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV> wrote:

Thanks. He is a better friend of Ann's.
Since March-in is for extramural inventions, OER has the lead and will coordinate with me in OSP and the funding IC. OTT is no longer involved.

Sent from my iPhone

On Jan 13, 2016, at 5:43 PM, Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov> wrote:

Hi Mark – Wanted to let you know that I received a call from a “old friend” of yours. James Love called to let me know that he is sending in a March-In Request to Dr. Collins for a Prostate Cancer Drug. He asked if he should send you a copy directly and I let him know that sending it to Dr. Collins was enough. It would be sent to the appropriate NIH offices for reply. When you get a chance, would you mind giving me a “lesson” on the March-In review process and how they have been handled in the past? Regards, Karen

*Karen L. Rogers
Acting Director, Office of Technology Transfer
Senior Royalties Administrator*

Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852
E-Mail: RogersK@nih.gov
Phone: 301-435-4359
Fax: 301-402-8678

SENSITIVE/CONFIDENTIAL INFORMATION

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To: Stevens, Ashley J <astevens@bu.edu>

Subject: data on university TT income

Ashley:

The data you presented at KEI on the % of TTOs that cover costs and ranges of income was helpful. Is that in print somewhere or available from AUTM?

Thanks,

Mark

Mark L. Rohrbaugh, Ph.D., J.D.

Special Advisor for Technology Transfer

Director, Division of Technology Transfer and Innovation Policy

Office of Science Policy

Office of the Director

National Institutes of Health

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHExchange/CN=OD/CN=ROHRBAUM]
Sent: 4/4/2017 4:22:59 PM
To: Stevens, Ashley J [astevens@bu.edu]
Subject: Re: data on university TT income

Thanks

Sent from my iPhone

> On Apr 4, 2017, at 12:12 PM, Stevens, Ashley J <astevens@bu.edu> wrote:
>
> One of mine, published in 2009 with the data from 2006.
>
> "How US Academic Licensing Offices are Tasked and Motivated - Is it all about the money?", Irene
Abrams, Grace Leung and Ashley Stevens, Research Management Review, 17.1, Fall/Winter 2009;
>
> Nothing since, but I have modeled it from the AUTM data once or twice - you have Net Income and can
assume 25% kept for expenses. You have Net Patent Expenses. You have staffing numbers and can assume a
mix and get salary levels from the AUTM salary survey, add 26% for overhead and 10% for all other office
expenses. When you do that, the numbers look pretty similar to the 2006 data.
>
> Best wishes,
>
> Ashley Stevens
> Focus IP Group, LLC
> Winchester, MA
>
> Office: (781) 721-2670
> Cell: [REDACTED] b6
>
> From: Rohrbaugh, Mark (NIH/OD) [E] [mailto:RohrBauM@od.nih.gov]
> Sent: Tuesday, April 4, 2017 11:42 AM
> To: Stevens, Ashley J <astevens@bu.edu>
> Subject: data on university TT income
>
> Ashley:
>
> The data you presented at KEI on the % of TTOs that cover costs and ranges of income was helpful. Is
that in print somewhere or available from AUTM?
>
> Thanks,
> Mark
>
> Mark L. Rohrbaugh, Ph.D., J.D.
> Special Advisor for Technology Transfer
> Director, Division of Technology Transfer and Innovation Policy
> Office of Science Policy
> Office of the Director
> National Institutes of Health
>
> <Abrams, Leung and Stevens.pdf>

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=591AB6B2424B4B8997082718CBB29FAB-ROHRBAUM]
Sent: 4/20/2018 4:01:55 PM
To: NIH TDC Long [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1266a38ae3aa4208baa3753f5054395f-NIH TDC Lon]
Subject: FW: KEI suing NIH over CAR-T license

(<https://www.keionline.org/27669>):

KEI sues NIH over license of CD30 CAR T patents to Gilead

Posted on April 19, 2018 by James Love

On April 19, 2018, KEI filed a lawsuit against the National Institutes of Health (NIH) to block or invalidate an exclusive license of patents on a new chimeric antigen receptor T-cell (CAR T) therapy to Gilead Sciences. A copy of the complaint is available here:

[KEIvNIH09319352421](#)

The license in question involves a set of patent applications regarding the development of a CD30 chimeric antigen receptor (CAR)-based immunotherapy using autologous (meaning one individual is both the donor and the recipient) T-cells, for the treatment of:

- Hodgkin lymphoma (HL),
- Non-Hodgkin's Lymphoma (NHL),
- diffuse large B cell lymphoma (DLBCL),
- peripheral T cell lymphoma not otherwise specified (PTCL-NOS),
- anaplastic large cell lymphoma (ALCL), and
- angioimmunoblastic T cell lymphoma (AITL).

The complaint stems from (1) the NIH's refusal to entertain an appeal from KEI on its intention to proceed with the proposed license even prior to KEI submitting the appeal itself, and (2) the self-proclaimed assertion by NIH that it is exempt from the requirement under 40 U.S.C. § 599 that creates a black letter obligation on federal agencies to seek the antitrust advice of the Attorney General prior to the disposal of federal property.

The complaint asserts that these acts constitute violations of the relevant law and regulations, including the Administrative Procedure Act.

The lawyers for KEI were Andrew Goldman of KEI, and Daniel Doty, an attorney in private practice in Baltimore.

For some additional context, see:

2018. January 5. [Briefing note on NIH proposed license to Gilead for CD-30 CAR T technology](#), KEIOnline.Org

2018. February 27. KEI Appeals NIH/NCI Decision to Proceed with License of CD30 CAR T technology to Gilead/Kite, KEIOnline.Org

Note also that last year Gilead paid \$11.9 billion to buy Kite Pharma, whose main assets were CD19-directed genetically modified autologous T-cell immunotherapy patents licensed from the NIH, and Celgene recently spent \$9 billion to buy Juno Therapeutics, whose main assets were also CAR T technologies also invented on NIH grants. In the current case the NIH is giving Gilead an exclusive license on CD30-directed genetically modified autologous T-cell immunotherapy patents, on the cheap, with no requirements on pricing or access.

Note further than the prices for the first two CAR T treatments (\$475,000 for Kymriah and \$373,000 for Yescarta) were so high that access has been limited.

Access to Medicine, Competition, Government Funded research Gilead Sciences, NIH

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=591AB6B2424B4B8997082718CBB29FAB-ROHRBAUM]
Sent: 8/8/2017 5:39:06 PM
To: Culhane, Ned (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7eaafc9ab644b3c8f00e05531c2e205-culhanee]; Berkson, Laura (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=adb561ab47e54fdc94e2a54682514434-berksonld]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Dodson, Sara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=985a956eaa0d4945bdcfd8ea30947d68-dodsonse]; Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]
Subject: Fwd: Int Bus. Times -- Bernie Sanders Tells Big Pharma: Stop Making Americans Pay Twice

Sent from my iPhone

Begin forwarded message:

From: "Mowatt, Michael (NIH/NIAID) [E]" <MMOWATT@niaid.nih.gov>
Date: August 8, 2017 at 12:56:54 PM EDT
To: "Feliccia, Vincent (NIH/NIAID) [E]" <VFeliccia@niaid.nih.gov>, "Frisbie, Suzanne (NIH/NIAID) [E]" <frisbies@otd.nci.nih.gov>, "Kirby, Tara (NIH/NIAID) [E]" <tara.kirby@nih.gov>, "Ranjan, Mukul (NIH/NIAID) [E]" <MRanjan@niaid.nih.gov>, "Sayyid, Fatima (NIH/NIAID) [E]" <fatima.sayyid@nih.gov>, "Williams, Richard (NIH/NIAID) [E]" <RWILLIAMS@niaid.nih.gov>
Cc: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Subject: Fwd: Int Bus. Times -- Bernie Sanders Tells Big Pharma: Stop Making Americans Pay Twice

FYI.

Begin forwarded message:

From: "Folkers, Greg (NIH/NIAID) [E]" <GFOLKERS@niaid.nih.gov>
Date: August 8, 2017 at 9:53:58 AM PDT
Subject: Int Bus. Times -- Bernie Sanders Tells Big Pharma: Stop Making Americans Pay Twice

Bernie Sanders Tells Big Pharma: Stop Making Americans Pay Twice

By [Josh Keefe @thejoshkeefe](#) On 08/07/17 AT 6:07 PM

While both political parties have denounced the rising cost of prescription drugs, neither Democrats nor Republicans have done much to address the problem. But this summer,

a new tool to restrict the rising prices of drugs developed with taxpayer dollars has been introduced by the two U.S. senators who don't belong to either party.

The mechanism works like this: Drug manufacturers who take federal money to develop drugs must keep their U.S. prices in line with the prices they charge in other economically advanced nations — typically much lower than drug prices in the U.S.

Read: *Democratic Governors' Fundraising Trails Republicans, Except When It Comes To Big Pharma*

The system would prevent pharmaceutical companies from effectively double-charging U.S. consumers by using their tax money for research and then charging them some of the steepest prices in the world at the pharmacy. Pharmaceutical companies, who pour millions of dollars into both the Democratic and Republican parties, are against the idea, which is perhaps why the fix is being pushed by Bernie Sanders of Vermont and Angus King of Maine, the only independents in congress.

The U.S. has the highest level of per capita pharmaceutical spending of any nation on Earth, according to the Organisation for Economic Co-operation and Development (OECD). And while Americans spend more than any other country to buy their drugs, they also spend more than any other country to develop those same drugs.

<image001.jpg>Senator Angus King (I-ME) asks questions at a Senate Intelligence Committee hearing on the Foreign Intelligence Surveillance Act (FISA) in Washington, D.C., June 7, 2017. King introduced an amendment into a military spending bill that would require drug makers keep drug prices in line with pharmaceutical costs in other countries. Photo: Reuters

In June, King successfully added an amendment to the 2018 military spending bill (still working its way through congress) that would allow the Department of Defense to take away exclusive patents from drug companies that benefitted from DoD funding if their drug price in the U.S. rises above the median price in seven foreign countries with similar economies.

Then last week, Sanders introduced legislation that would tie the prices of drugs made with government funding to costs in other countries. Unlike King's amendment, Sanders' bill would expand the concept beyond the DoD. The bill requires companies taking federal funds to develop drugs to enter into "reasonable pricing" agreements with the Secretary of Health and Human Services.

"Under this insane system, Americans pay twice. First we pay to create these lifesaving drugs, then we pay high prices to buy those drugs," wrote Sanders in a New York Times op-ed. "Our government must stop being pushovers for the pharmaceutical industry and its 1,400 lobbyists."

The bill defines a "reasonable price" as no more than the lowest prices charged in countries with GDP and per capita income similar to the U.S. (The bill specifically pegs pricing to countries in the Organization for Economic Co-Operation and Development.)

The proposal is the latest salvo in Sanders' effort to stop the military from granting French pharmaceutical company Sanofi Pasteur the exclusive right to sell a Zika vaccine.

“The days of allowing Sanofi and other drug makers to gouge American consumers after taking billions in taxpayer money must end,” Sanders told HuffPost this week. “That is why I am introducing legislation to demand fairer, lower prices for the Zika vaccine and for every drug developed with government resources.”

But just how much government support the industry receives is up for debate. While industry estimates put total annual private R&D spending by biopharmaceutical companies at about \$60 billion per year, the government’s contribution is much harder to nail down. The National Institutes of Health, the government’s main funder of health research, told International Business Times in a statement that “there is no exact number which would accurately capture NIH investment” in drug development. In total, NIH spends about \$32 billion on medical research annually.

Last year, the National Center for Science and Engineering Statistics estimated that in 2014, total federal government R&D spending on pharmaceuticals and medicines was just \$267 million. But that number takes into account only money given directly to drug makers.

“Federal support of biopharma R&D isn’t going to take the form of big checks cut to companies,” Scott Hinds, a pharmaceutical industry analyst for investment research firm Sector and Sovereign Research told IBT in an email. “Rather, it’s going to come through funding grants and research for academics, government employees and other non-industry scientists.”

“Typically, then, if anything of commercial value is discovered in this sponsored research, those compounds will be sold or licensed to drug companies who have the capital and resources to spend on later phase (more expensive) clinical development necessary to bring them to market,” Hinds said.

Other experts told IBT federal support of drug development goes well beyond just funding research.

“It’s not so much the money we are actually spending through NIH. We are providing huge value to companies in tax credits, other incentives, expedited FDA approval, exclusivity agreements... all of these are benefits,” Rachel Sachs, an associate professor at the Washington University in St. Louis School of Law told IBT.

Sachs cited a 50 percent tax credit for the development of “orphan” drugs as an example of the government’s support of the pharmaceutical industry. The value of that orphan drug tax credit is estimated to be worth \$50 billion between 2016 and 2025, according to the Treasury Department.

But the benefits flow both ways between the pharmaceutical industry and Washington, which is why the Sanders bill faces an uphill battle to reach the floor for a vote. The bill was sent to the Senate Health, Education, Labor, and Pensions committee, which is chaired by Lamar Alexander. Pharmaceutical and health products companies gave more to Alexander’s campaigns between 2011 and 2016 than did any other industry, according to the Center for Responsive Politics. And even if the bill gets to the floor, it would face opposition from the industry’s 1,350 lobbyists, who don’t come cheap. The pharmaceutical and health products industry has spent a remarkable \$144 million on lobbying so far in 2017, more than double what the defense industry has spent over the same time period.

“Proposals to insert a reasonable pricing clause ignore the substantial R&D investments and risks undertaken by the private sector in developing and bringing a new medicine to patients,” the Pharmaceutical Research and Manufacturers of America (PhRMA), which has spent \$14 million on lobbying so far this year, told IBT in a statement. “Such proposals undermine critical intellectual property rights and incentives, create substantial uncertainty for companies and establish completely arbitrary criteria for taking intellectual property. This could chill critically needed collaborations and investment by the private sector to address some of our most serious unmet medical needs.”

The pharmaceutical industry, which says it costs \$2.6 billion to bring a drug to market (while spending more on marketing than research) made a similar argument against “reasonable pricing” more than two decades ago, when it successfully persuaded the Clinton administration to repeal a “reasonable pricing” rule implemented by President George H.W. Bush.

Read: Bernie Sanders’ Drug Price Bill Would Save Billions, Congressional Analysts Say

After the 1980 Bayh-Dole Act, private researchers could patent intellectual property they developed using federal funding. But by the late 1980s, outrage over the \$8,000 annual cost of AIDS drug AZT, which was the only drug approved for treatment of the disease at the time, prompted the Bush administration to implement price control measures. In 1989, NIH was granted the right to review the introductory prices of drugs that were produced with government research, over the objections of the pharmaceutical industry.

“The Bush administration felt it was appropriate to expect some concessions on pricing if the government was involved in the drug and funding research,” James Love, director of Knowledge Ecology International, told IBT. Love researched the original rule while working for Ralph Nader’s Center for the Study of Responsive Law in the early 1990s.

But unlike the specific criteria for reasonable pricing put forth in the Sanders bill, the Bush rule was a bit ambiguous. “The agreements said something to the effect that it had to show some relationship between price and government’s role in developing the drug... Nobody really knew what it meant,” Love said.

Just six years later, the Clinton administration rescinded the order on the grounds that it was harmful to innovation.

“The pricing clause has driven industry away from potentially beneficial scientific collaborations... without providing an offsetting benefit to the public,” NIH Director Dr. Harold Varmus said at the time. “Eliminating the clause will promote research that can enhance the health of the American people.”

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Thx

On Nov 7, 2016, at 9:28 AM, Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov> wrote:

Begin forwarded message:

Update on today's meeting with KEI:
Barb won't be joining and it will be just you, me, and Kathy.

b5

From: Rohrbaugh, Mark (NIH/OD) [E] [RohrBauM@OD.NIH.GOV]
Sent: 7/25/2017 5:42:52 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: Fwd: Prospective Grant of Exclusive Patent License: Production of Attenuated West Nile Virus Vaccines

What would you suggest?

b5

b5

Thanks
Mark

Sent from my iPhone

Begin forwarded message:

From: "Soukas, Peter (NIH/NIAID) [E]" <peter.soukas@nih.gov>
Date: July 24, 2017 at 1:52:16 PM EDT
To: "Puglielli, Maryann (NIH/NIAID) [E]" <maryann.puglielli@nih.gov>, "Williams, Richard (NIH/NIAID) [E]" <RWILLIAMS@niaid.nih.gov>, "Mowatt, Michael (NIH/NIAID) [E]" <MMOWATT@niaid.nih.gov>, "Frisbie, Suzanne (NIH/NIAID) [E]" <frisbies@otd.nci.nih.gov>
Cc: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Subject: FW: Prospective Grant of Exclusive Patent License: Production of Attenuated West Nile Virus Vaccines

FYI, thanks. I will need your guidance in preparing a response.

Peter Soukas
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Technology Transfer and Intellectual Property Office
Suite 6D
5601 Fishers Lane, MSC9804
Rockville, MD 20852-9804
Phone: 301-594-8730
Fax: 240-627-3117
Email: ps193c@nih.gov

From: jamespackardlove@gmail.com [mailto:jamespackardlove@gmail.com] **On Behalf Of** Jamie Love
Sent: Sunday, July 23, 2017 3:17 AM
To: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>
Subject: Prospective Grant of Exclusive Patent License: Production of Attenuated West Nile Virus Vaccines

Peter Soukas
Technology Transfer and Patent Specialist
Technology Transfer and Intellectual Property Office
National Institute of Allergy and Infectious Diseases
National Institutes of Health, 5601 Fishers Lane,
Suite 6D, Rockville, MD 20852-9804;

Telephone: (301) 594-8730;

REL0000024808

Facsimile: (240) 627-3117

Via

Email: ps193c@nih.gov;

Dear Peter Soukas,

KEI would like to know the following.

1. Has this license been signed by the NIH?
2. What is the royalty rate and term of years for the license?
3. Were there any objections to the exclusive license?
4. Did the NIH include any provisions to ensure access to the vaccine at affordable prices?
5. Will the vaccine be manufactured in the United States?
6. Has the NIH provided any funding to The International Medica Foundation?
7. Will the NIH provide for reporting on R&D costs associated with the development of the vaccine, for the public?

James Love
Knowledge Ecology International

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,

twitter.com/jamie_love

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 11/7/2016 2:26:48 PM
To: Baker, Rebecca (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Bakerrg]
CC: Wolinetz, Carrie (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wolinetzcdc9a]
Subject: Re: time sensitive request: talking points for today's xtandi meeting

Ok

Sent from my iPhone

On Nov 7, 2016, at 9:18 AM, Baker, Rebecca (NIH/OD) [E] <bakerrg@od.nih.gov> wrote:

Hi Mark,

Update on today's meeting with KEI:

Barb won't be joining and it will be just you, me, and Kathy.

b5

Thanks,
Rebecca

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 4/14/2017 6:34:56 AM
To: Mamacos, Peter (HHS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Peter.Mamacos.OS]
Subject: Re: Bayh-Dole points

b5

Sent from my iPhone

> On Apr 14, 2017, at 1:37 AM, Mamacos, Peter (HHS/OGA) <Peter.Mamacos@hhs.gov> wrote:
>
> than

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 11/21/2016 1:35:09 PM
To: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: Re: Did you meet with KEI?

KH did and asked me to sit in. Just listened

Sent from my iPhone

On Nov 21, 2016, at 7:23 AM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:

--

Ann M. Hammersla, J.D.
Director
Division of Extramural Inventions and Technology Resources
Office of Policy for Extramural Research Administration
Rockledge 1, Suite 310
6705 Rockledge Drive
Bethesda, Maryland 20892-7974
PHONE: 301-435-0745

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 4/26/2016 12:46:26 PM
To: Baker, Rebecca (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Bakerrg]
CC: Wolinetz, Carrie (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wolinetzcdc9a]; Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: Fwd: Two more letter on Xtandi/march-in (addressed to Dr. Collins)
Attachments: 1 See attached offer to supply low cost enzalutamide.msg; ATT00001.htm; 1a RN-LettertoFrancisCollins-22April2016.pdf; ATT00002.htm

Rebecca:

Do you know whether KH wants [REDACTED] b5
[REDACTED] b5

Mark

Sent from my iPhone

Begin forwarded message:

From: "Marshall, Lisa (NIH/OD) [E]" <MarshallL@od.nih.gov>
Date: April 26, 2016 at 8:22:59 AM EDT
To: "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>
Subject: Two more letter on Xtandi/march-in (addressed to Dr. Collins)

Hi Dr. Rohrbaugh,

Dr. Collins received the attached two letters yesterday. [REDACTED] b5

[REDACTED] b5 I wanted to make sure [REDACTED] b5
[REDACTED] b5
[REDACTED] b5 Thanks for your help, Lisa

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 4/19/2016 1:13:50 PM
To: Shmilovich, Michael (NIH/NHLBI) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ShmilovichM]
Subject: Re: Boron Neutron technologies, licensed to Beijing Lanyears Communication Technology, Ltd., a company formed under the laws of the People's Republic of China and having its principle place of business in Beijing, China.

Or send me what you have and we can work on it together. I wanted Dale's input but not sure if he is back from vacation yet

Sent from my iPhone

On Apr 19, 2016, at 8:13 AM, Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov> wrote:

Hi Mark -- Sue and I discussed KEI yesterday, I had a [REDACTED] in mind but was told that you are [REDACTED] Let me know.

Regards,

Michael A. Shmilovich, Esq., CLP
National Heart, Lung, and Blood Institute
Office of Technology Transfer and Development
31 Center Drive Room 4A29, MSC2479
Bethesda, MD 20892-2479
o. 301.435.5019
Skype ID: shmilovich.nihott
shmilovm@mail.nih.gov

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From: Shmilovich, Michael (NIH/NHLBI) [E]
Sent: Tuesday, April 19, 2016 8:05 AM
To: Ano, Susan (NIH/OD) [E]
Subject: FW: Boron Neutron technologies, licensed to Beijing Lanyears Communication Technology, Ltd., a company formed under the laws of the People's Republic of China and having its principle place of business in Beijing, China.

lol. looks like they have an opinion after all

Michael A. Shmilovich, Esq., CLP
National Heart, Lung, and Blood Institute
Office of Technology Transfer and Development
31 Center Drive Room 4A29, MSC2479
Bethesda, MD 20892-2479
o. 301.435.5019
Skype ID: shmilovich.nihott
shmilovm@mail.nih.gov

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From: jamespackardlove@gmail.com [jamespackardlove@gmail.com] on behalf of Jamie Love [james.love@keionline.org]
Sent: Monday, April 18, 2016 10:38 PM

REL0000024828

To: Shmilovich, Michael (NIH/NHLBI) [E]

Subject: RE: Boron Neutron technologies, licensed to Beijing Lanyears Communication Technology, Ltd., a company formed under the laws of the People's Republic of China and having its principle place of business in Beijing, China.

Attached are our comments on proposed licenses to Beijing Lanyears.

Jamie

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,

twitter.com/jamie_love

<BoronNeutronBeijingLanyears.pdf>

From: Bradley, David (NIH/NIDCR) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4232AB2D5334498BA86ABBCEC1E39784-BRADLEYDA]
Sent: 7/18/2018 4:44:29 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: Documents for Review
Attachments: Yun Mei, July 9, 2018, NIH license to ERYTHRYx Therapeutics.pdf; KEI Letter_A-237-2018.pdf

David William Bradley, Ph.D.
Director, Office of Technology Transfer and Innovation Access (OTTIA)
National Institute of Dental and Craniofacial Research (NIDCR)
BLDG 1DEM RM 687-K
6701 DEMOCRACY BLVD, MSC 4878
BETHESDA MD 20817-4878
bradleyda@nidcr.nih.gov
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954.435.4824 (land line)
[b6] (cell)

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NIDCR Staff, please submit New Tech Transfer Requests through our website:

<https://nidcrintranet.nidcr.nih.gov/DIR/OSD/techtransfer/datalink/Site%20Pages/TTServiceRequests-Requesters.aspx>



July 9, 2018

Yun Mei
Technology Transfer and Patent Specialist
Office of Technology Transfer and Innovation Access
National Institute of Dental and Craniofacial Research
National Institutes of Health
Email: yun.mei@nih.gov.

Re: Prospective Grant of an Exclusive Patent License: Methods of Modulating Erythropoiesis With Arginine Vasopressin Receptor 1B Molecules, to ERYTHRYx Therapeutics. Notice for comment published in 83 FR 29127.

Dear Yun Mei,

Knowledge Ecology International (KEI) offers the following comments on the, "Prospective Grant of an Exclusive Patent License: Methods of Modulating Erythropoiesis With Arginine Vasopressin Receptor 1B Molecules," to ERYTHRYx Therapeutics, which was noticed in the Federal Register (83 FR 29127).

The patents described in the notice are as follows:

1. U.S. Provisional Patent Application No. 61/885,258, filed October 1, 2013 and entitled "Methods of Modulating Erythropoiesis with Arginine Vasopressin Receptor 1B Molecules" (HHS Reference No. E-619-2013-0-US-01);
2. PCT Application No. PCT/US2014/058613, filed October 1, 2014 and entitled "Methods of Modulating Erythropoiesis with Arginine Vasopressin Receptor 1B Molecules" (HHS Reference No. E-619-2013-0-PCT-02); and
3. U.S. Patent Application No. 15/022,531, filed March 16, 2016 and entitled "Methods of Modulating Erythropoiesis with Arginine Vasopressin Receptor 1B Molecules" (HHS Reference No. E-619-2013-0-US-03).

The field of use may be limited to "Use of arginine vasopressin receptor 1B agonists to treat anemia caused by (i) chronic renal failure on dialysis, (ii) receiving myelosuppressive chemotherapy, or (iii) lacking antidiuretic hormone."

We assume, from the FR notice, the geographic area for the license to ERYTHRYx Therapeutics will only cover the United States, although we do note the PCT application, which

started the national phase at the European Patent Office (EPO) in March 2016¹, which makes it seem as though some other countries may be relevant.

Since the drug is already on the U.S. market (as mentioned in the FR notice), we oppose the granting of an exclusive license, absent some explanation of why a monopoly needs to be granted for the three patented inventions held by the NIH, in order to find new uses for an older drug.

We assume that the purpose of the exclusive license is to allow ERYTHRYx Therapeutics to charge high prices in the United States, on an older generic drug, all while the invention was funded and owned by the NIH. This raises several questions, including for starters, who is the company looking to obtain this legal monopoly?

It appears as though ERYTHRYx Therapeutics was created in January 2018. According to documents filed with the State of California, the type of business is “patent holding.”

<https://businesssearch.sos.ca.gov/Document/RetrievePDF?Id=201803210059-23772691>

We cannot find a web page for the company. James Schaeffer (listed as Manager on the LLC form linked above) appears to be a VP of External Relations at California Institute for Biomedical Research and a former Merck employee, and perhaps you can confirm that, and also tell us if there are any current or former NIH officials involved in the company, as employees or shareholders.

Should the NIH give this monopoly to the shell company ERYTHRYx Therapeutics, at a very minimum, the licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product that uses the invention, including reporting separately and individually the outlays on each clinical trial. Here we note that this is different from asking the licensee to provide the public access to its business plan. We are asking for data going forward, and for actual outlays on R&D, rather than planned outlays.

The NIH should also consider adding conditions in the license to protect the public from both non-use of the invention, and unreasonable use.

Without knowing more about the current state of development for the repurposed drug, or the investments needed to expand FDA approval for the drug, it may be challenging for the NIH to set such conditions, but regardless, the NIH has a responsibility to limit the use of exclusive licenses and the scope of rights granted in any exclusive license, under 35 USC § 209, and also to seek the advice of the Attorney General, pursuant to 40 USC § 599.

¹ <https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2015050983>

For the NIH to enable citizens to comment usefully on these proposed exclusive licenses, the NIH needs to provide more context to justify the exclusive nature of the license, and the terms of the license themselves. For example, the NIH should explain in lay terms, how much money the government has spent on the inventions so far, and how much additional investment is estimated to be necessary to further commercialize the products. Also, it would be useful to know if the NIH is licensing any rights in test data that may be relevant to the registration of repurposed drug, since the FDA regulatory test data protections provide non-patent incentives that may be relevant.

We note for that small molecule test data, the FDA grants five years of exclusive rights to rely upon data when the tests involve novel drugs, and three years when the tests involve a new use for an existing drug.

In this case, for a patent on a repurposed drug to a shell company with no visible operations, a shorter term of license would be more appropriate than a life-of-patent license. The HHS policy in the early 1980s was to permit an initial exclusive term of 5 years, subject to the possibility of an extension upon a showing that the extended term was justified.

Finally, during the period of exclusivity the price should bear some relationship to the risks and costs of obtaining FDA approval for a new indication. The NIH could include in the license a provision that the price should be sufficiently reasonable that for most private insurance plans, the drug is considered a Tier 1 or Tier 2 medication, and also that the company selling the drug as a monopoly for the patented repurposed use have a sufficiently robust patient assistance program to ensure the drug is accessible to persons without insurance or with inadequate insurance, a possible situation that seems quite relevant looking forward.

Sincerely,

A handwritten signature in cursive script that reads "James Love". The signature is written in dark ink and is positioned above the typed name and contact information.

James Love
Knowledge Ecology International
1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
Tel.: (202)332-2670
James.Love@keionline.org



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Dental
and Craniofacial Research
Bethesda, Maryland 20892

July 13, 2018

James Love
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009
James.Love@keionline.org

IN RE: 83 Federal Register 29127 (June 22, 2018), "Prospective grant of an exclusive patent license: Methods of modulating erythropoiesis with arginine vasopressin receptor 1B molecules"

Dear James Love:

Thank you for providing us with your comments regarding the notice of the proposed license the National Institute of Dental and Craniofacial Research intended to grant to ERYTHRYx Therapeutics. Prior to posting a notice for a proposed grant of an exclusive license, the NIH determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company is qualified both technically and financially to be granted an exclusive license to the Government's intellectual property in the fields of use as specified. The notice period provides an opportunity for public comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license and have considered your comments.

With respect to your request for various reports, it is not consistent with our mission to create reports requested by the public. If your organization is requesting documents, such requests should be filed under the Freedom of Information Act. The webpage for the NIH FOIA Office provides more information on filing requests: www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests

Sincerely,

David W. Bradley -S

Digitally signed by David W.
Bradley -S
Date: 2018.07.13 13:23:43 -04'00'

David W. Bradley, Ph.D.
Director
Office of Technology Transfer and Innovation Access
National Institute of Dental and Craniofacial Research
National Institutes of Health

REL0000024830.0002

From: Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]
Sent: 7/16/2019 11:09:52 AM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Inquiry re: Proposed Exclusive Licenses on CD19 and CD20-related therapies to Kite

Please see below for your records.

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
Phone (direct): (240) 276-6467
Fax: 240-276-5504

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From: Lambertson, David (NIH/NCI) [E]
Sent: Tuesday, July 16, 2019 7:09 AM
To: 'Claire Cassedy' <claire.cassedy@keionline.org>
Subject: RE: Inquiry re: Proposed Exclusive Licenses on CD19 and CD20-related therapies to Kite

Ms. Cassedy,

Thank you for your inquiry. Below you will find my response to questions # 6, 8 and 9. The other questions either have been answered previously or are not related to the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) regarding a decision by a federal agency to grant an exclusive license.

Question 6- The technology under this proposed license is generally related to at least one previous license in that they are both directed to a method of treating hematological malignancies with a chimeric antigen receptor. It differs from the previous one in having the potential as an adjunct or alternative therapy for certain cancer patients.

Question 8- The E-205-2018-0 technology has been advertised as available for licensing since November 2018.

Question 9- Since the technology was advertised, this question is not applicable.

Regards,

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager

REL0000024831

Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
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Fax: 240-276-5504

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From: Claire Cassedy <claire.cassedy@keionline.org>
Sent: Friday, July 12, 2019 2:04 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: Inquiry re: Proposed Exclusive Licenses on CD19 and CD20-related therapies to Kite

Dear Dr. Lambertson,

I am writing in reference to the Federal Register notices 84 FR 33272 and 84 FR 33270 regarding, "Prospective Grant of an Exclusive Patent License: Autologous Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20" and "Prospective Grant of an Exclusive Patent License: Allogeneic Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20," for which you are listed as the contact for inquiries. I was hoping you could provide me with some further information regarding the status of the technologies.

1. At what stage of development are the inventions listed?
2. Has the government funded any clinical trials relevant to these technologies?
3. If the government has provided funding, how much has been spent by the government on these trials? Can you provide NCT numbers?
4. Is the term in the proposed licenses to be life of patent or less than life of patent?
5. In working towards executing this license, has the NIH sought advice from the Attorney General (as is required under 40 USC § 559) to determine if the "disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law"?
6. Considering the NIH has previously licensed CAR T technologies to Kite Pharma/Gilead, are the technologies identified in the current Federal Register notice related in any way to the previously executed licenses? (*List of previously noticed exclusive licenses on CAR T technologies to Kite Pharma follows below this email*)
7. Is there a Cooperative Research and Development Agreement associated with this technology?
8. Did the NIH previously post this technology in the Federal Register under "Government Inventions available for licensing"? And/or was it announced on any other platform that these technologies were available for licensing?
9. If not, how was it determined that Kite would enter into this proposed exclusive license, particularly considering the technology is currently under a provisional patent application?
10. Considering Kite/Gilead currently has CAR T therapy Yescarta (axicabtagene ciloleucel) on the market at a price of \$373,000, has/will the NIH seek license terms that will ensure the resultant therapy is available to patients on reasonable terms?

Thank you in advance for your assistance in this matter.

Sincerely,

Claire Cassedy

Previously noticed exclusive licenses on CAR T technologies to Kite Pharma:

Prospective Grant of Exclusive License: Development of T Cell Receptors and Chimeric Antigen Receptors Into Therapeutics for Adoptive Transfer in Humans To Treat Cancer

<https://www.federalregister.gov/documents/2012/01/24/2012-1383/prospective-grant-of-exclusive-license-development-of-t-cell-receptors-and-chimeric-antigen>

Prospective Grant of Exclusive License: Development of T Cell Receptors for Adoptive Transfer in Humans to Treat Cancer

<https://www.federalregister.gov/documents/2014/03/25/2014-06412/prospective-grant-of-exclusive-license-development-of-t-cell-receptors-for-adoptive-transfer-in>

Prospective Grant of Exclusive License: Development of T Cell Receptors for Adoptive Transfer in Humans To Treat Cancer

<https://www.federalregister.gov/documents/2014/10/16/2014-24502/prospective-grant-of-exclusive-license-development-of-t-cell-receptors-for-adoptive-transfer-in>

Prospective Grant of Exclusive License: The Development of an Anti-CD19 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancers

<https://www.federalregister.gov/documents/2015/06/26/2015-15657/prospective-grant-of-exclusive-license-the-development-of-an-anti-cd19-chimeric-antigen-receptor-car>

Prospective Grant of Exclusive Patent License: Development of T Cell Receptors (TCRs) Targeting the KRAS G12D Mutation for the Treatment of Cancer

<https://www.federalregister.gov/documents/2016/08/17/2016-19549/prospective-grant-of-exclusive-patent-license-development-of-t-cell-receptors-tcrs-targeting-the>

Prospective Grant of Exclusive Patent License: Development of Anti-CD70 Chimeric Antigen Receptors for the Treatment of CD70 Expressing Cancers

<https://www.federalregister.gov/documents/2016/10/05/2016-24030/prospective-grant-of-exclusive-patent-license-development-of-anti-cd70-chimeric-antigen-receptors>

Prospective Grant of an Exclusive Patent License: The Development of an Anti-CD30 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

<https://www.federalregister.gov/documents/2017/12/20/2017-27416/prospective-grant-of-an-exclusive-patent-license-the-development-of-an-anti-cd30-chimeric-antigen>

—
Claire Cassidy
Knowledge Ecology International
1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
Tel.: 1.202.332.2670

From: Freel, Rose (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8AE9AAB7E3249E881BB573E9A189036-FREELRM]
Sent: 7/10/2018 6:23:45 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: KEI letter regarding 83 FR 30448
Attachments: KEI_LetterResponsetoExtensionRequest_7.10.2018.pdf

Hi Mark,

See attached for the final letter I sent to KEI.

Best,
Rose

--

Rose Santangelo Freel, Ph.D.
Technology Transfer Manager
National Cancer Institute
P 301-624-1257 | rose.freel@nih.gov

From: Freel, Rose (NIH/NCI) [E]
Sent: Tuesday, July 10, 2018 2:23 PM
To: 'Luis Gil Abinader' <luis.gil.abinader@keionline.org>
Cc: Jamie Love <james.love@keionline.org>; Andrew S. Goldman <andrew.goldman@keionline.org>
Subject: RE: KEI letter regarding 83 FR 30448

Dear Mr. Abinader,

Please find attached a letter in response to your request.

Best Regards,
Rose

--

Rose Santangelo Freel, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute
P 301-624-1257 | rose.freel@nih.gov

From: Luis Gil Abinader [<mailto:luis.gil.abinader@keionline.org>]
Sent: Monday, July 09, 2018 1:21 PM
To: Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>
Cc: Jamie Love <james.love@keionline.org>; Andrew S. Goldman <andrew.goldman@keionline.org>
Subject: KEI letter regarding 83 FR 30448

Dear Dr. Freel,

Attached please find a letter to you on behalf of Knowledge Ecology International (KEI).

Best regards,

REL0000024832

Luis Gil Abinader



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Technology Transfer Center
8490 Progress Drive
Riverside 5 building, Suite 400
Frederick, MD 21701
Phone (301) 624-8775
FAX (301) 631-3033

via email only

July 10, 2018

Luis Gil Abinader
Knowledge Ecology International (KEI)
1621 Connecticut Avenue, Suite 500,
Washington DC 20009
luis.gil.abinader@keionline.org

RE: Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin
Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer (83 FR 30448)

Dear Mr. Abinader,

We received your July 9, 2018 request to extend the deadline for comments on 83 FR 30448. After careful review and consideration of your letter, we are denying your request for an extension.

We do not agree that the information you are seeking will affect our decision or the contours of this proposed license, and an extension will only delay the timely delivery of what may be lifesaving therapies to patients.

KEI may submit comments and/or an application for a license for consideration on or before the close of the comment period listed in the Notice.

Sincerely,

b6

Rose M. Freel, Ph.D.
Senior Technology Transfer Manager
NCI Technology Transfer Center

REL0000024832.0001

From: Greene, Jaime (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E06E39F0BCD34511A92DF20C5DC8722A-GREENEJAIME]
Sent: 7/17/2018 9:54:13 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FYI email from KEI
Attachments: Re: Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Hematological Cancers. Notice for comment published in 83 FR 22501; Re: Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Hematological Cancers. Notice for comment published in 83 FR 22501; Re: Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Hematological Cancers. Notice for comment published in 83 FR 22501; Re: Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Hematological Cancers. Notice for comment published in 83 FR 22501; Re: Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Hematological Cancers. Notice for comment published in 83 FR 22501

Hi Mark,

FYI, I received these five emails (attached) from KEI today as follow-ups to my official response to their comments to a FR notice. KEI's comments about the typo are incorrect. There were no misspellings of the company name in either the FR notice or the letter to KEI.

I showed them to Richard, and we do not plan to respond.

Best,
Jaime

Jaime Meredith Greene, M.S.
Senior Technology Transfer Manager
NCI Technology Transfer Center

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REL0000024833

From: James Love [james.love@keionline.org]
Sent: 7/16/2018 10:04:10 PM
To: Greene, Jaime (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e06e39f0bcd34511a92df20c5dc8722a-greenejaime]; Claire Cassedy [claire.cassedy@keionline.org]; Luis Gil Abinader [luis.gil.abinader@keionline.org]; Manon Ress [manon.ress@keionline.org]; Thiru Balasubramaniam [thiru@keionline.org]
Subject: Re: Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Hematological Cancers. Notice for comment published in 83 FR 22501

Luis say their Twitter account was created on February 2018. <https://twitter.com/MorphiexBio> The first tweet was sent June 1, 2018. Our comments on the license were filed on May 30.

Jaime, I don't mind you rejecting our comments, but pretending that there was much information available about the company before the FR notice is not accurate, and hardly explains why you ignored every issue we raised, other than the very recently created and almost devoid of content web page.

Apparently Anthony Schwartz, the Morphiex CEO, is a former NIH employee, but I'm guessing you know that.

<https://twitter.com/aschwartzphd?lang=en>

anthony.schwartz@nih.hhs.gov
http://nihzilla.com/nih-employee/contact/anthony-schwartz-301_594_5390
<https://www.linkedin.com/in/anthonyschwartzphd>

On Mon, Jul 16, 2018 at 5:16 PM, James Love <james.love@keionline.org> wrote:
This is the company news page.

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Dear Mr. Love,

Thank you for your comments with regard to the Notice of Prospective Grant of an Exclusive License to Morphix Biotherapeutics for NIH technology reference no. E-227-2006.

We have considered your comments and provide the attached response.

Best,

Jaime

Jaime Meredith Greene, M.S.
Senior Technology Transfer Manager

NCI Technology Transfer Center

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To: Greene, Jaime (NIH/NCI) [E] <greenejaime@mail.nih.gov>
Subject: Morphix license

Dear Jaime Greene,
I believe this mail bounced for some reason yesterday.
Jamie

Jaime M. Greene
Senior Licensing and Patenting Manager
NCI Technology Transfer Center
Email: greenejaime@mail.nih.gov.
Date: May 30, 2018

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- B. The NIH limits the scope of rights for the exclusivity to only those rights reasonably necessary to induce investments for the development and practical application of the invention, and in particular, that the field of use is sufficiently narrow, that the term of the exclusivity is sufficiently limited, and that the license contains sufficient safeguards to ensure that the invention is "available to the public on reasonable terms," as is required by 35 USC § 209 and 35 USC § 201(f).

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Subject: Re: Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Hematological Cancers. Notice for comment published in 83 FR 22501
Attachments: Screenshot 2018-07-16 at 5.15.23 PM.png

This is the company news page.

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Jamie

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Dear Mr. Love,

Thank you for your comments with regard to the Notice of Prospective Grant of an Exclusive License to Morphix Biotherapeutics for NIH technology reference no. E-227-2006.

We have considered your comments and provide the attached response.

Best,

Jaime

Jaime Meredith Greene, M.S.
Senior Technology Transfer Manager

NCI Technology Transfer Center

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REL0000024833.0002

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Sent: Thursday, May 31, 2018 11:29 AM
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Subject: Morphix license

Dear Jaime Greene,
I believe this mail bounced for some reason yesterday.
Jamie

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Email: greenajaime@mail.nih.gov.
Date: May 30, 2018

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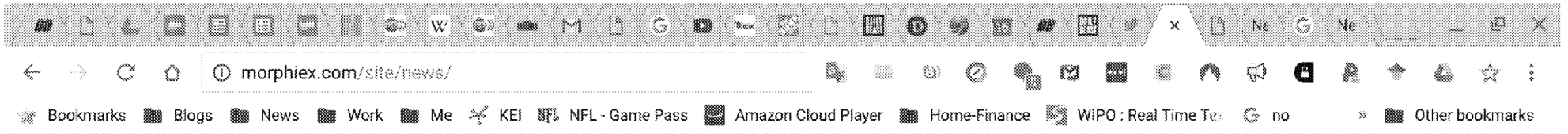
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No posts were found.

LOCATION

75 Arlington St. Suite 5005
Boston, MA
info@morphiex.com

SOCIAL MEDIA



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Subject: Re: Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Hematological Cancers. Notice for comment published in 83 FR 22501

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From: James Love [james.love@keionline.org]
Sent: 7/16/2018 9:01:29 PM
To: Greene, Jaime (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e06e39f0bcd34511a92df20c5dc8722a-greenejaime]; Claire Cassedy [claire.cassedy@keionline.org]; Luis Gil Abinader [luis.gil.abinader@keionline.org]; Manon Ress [manon.ress@keionline.org]; Thiru Balasubramaniam [thiru@keionline.org]
Subject: Re: Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Hematological Cancers. Notice for comment published in 83 FR 22501

Dear Jaime,

If the NIH thought that it was granting a license to Morphix, but instead is signing a contract with Morphix, it may need to redouble the due diligence on this license, or fix the Federal Register Notice.

Jamie

On Mon, Jul 16, 2018 at 4:12 PM, Greene, Jaime (NIH/NCI) [E] <greenejaime@mail.nih.gov> wrote:

Dear Mr. Love,

Thank you for your comments with regard to the Notice of Prospective Grant of an Exclusive License to Morphix Biotherapeutics for NIH technology reference no. E-227-2006.

We have considered your comments and provide the attached response.

Best,

Jaime

Jaime Meredith Greene, M.S.
Senior Technology Transfer Manager

NCI Technology Transfer Center

Note: This email may contain confidential information. If you are not the intended recipient, any disclosure, copying or use of this email or the information enclosed therein is strictly prohibited, and you should notify the sender for return of any attached documents

From: James Love [mailto:james.love@keionline.org]
Sent: Thursday, May 31, 2018 11:29 AM
To: Greene, Jaime (NIH/NCI) [E] <greenejaime@mail.nih.gov>
Subject: Morphix license

Dear Jaime Greene,
I believe this mail bounced for some reason yesterday.
Jamie

Jaime M. Greene
Senior Licensing and Patenting Manager
NCI Technology Transfer Center

Email: greenejaime@mail.nih.gov.

Date: May 30, 2018

Re: Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Hematological Cancers. Notice for comment published in [83 FR 22501](#).

Dear Jaime Greene:

Knowledge Ecology International (KEI), HealthGap and the Union for Affordable Cancer Treatment (UACT) are organizations concerned about drug pricing and access to patented medicines, offering comments on the grant of an exclusive license of the National Institutes of Health (NIH) patents noticed in [83 FR 22501](#), to Morphix Biotherapeutics (“Morphix”) located in Boston, MA. The above entities oppose the issuing of the license unless:

- A. The NIH has determined that an exclusive license is “a reasonable and necessary incentive” to induce investments for the development and practical application of the invention, as is required by 35 USC § 209, and shares its analysis with the public; and
- B. The NIH limits the scope of rights for the exclusivity to only those rights reasonably necessary to induce investments for the development and practical application of the invention, and in particular, that the field of use is sufficiently narrow, that the term of the exclusivity is sufficiently limited, and that the license contains sufficient safeguards to ensure that the invention is “available to the public on reasonable terms,” as is required by 35 USC § 209 and 35 USC § 201(f).

Morphix Biotherapeutics does not appear to have a web page, and there is almost no information available about the company, other than a February 27, 2018 registration of the company in Delaware. As of May 23, 2018, the company Facebook page had only one entry, which was just a logo and no text. One imagines that such a company may also have few assets, yet the NIH is proposing an exclusive license of inventions that have a potential for the treatment, prevention, and diagnosis of hematological cancers.

Our comments address three areas of concern, (1) the pricing, affordability and access issues, (2) freedom for researchers to use the inventions, and (3) requirements for transparency of the development and commercialization of the medicine.

We propose the following safeguards regarding the pricing of and access to products that use the inventions:

1. Products are priced no higher in the United States than the median price charged in the seven largest economies as measured by nominal GNI that have a nominal GNI per capita of at least 50 percent of the United States. To fully appreciate our concerns about the discriminatory pricing that makes US residents pay more than everyone else, please review the cross country price comparisons here: <http://drugdatabase.info/drug-prices/>
2. Prices for products in the United States do not exceed the estimated value of the treatment, as determined by independent health technology assessments selected by Department of Health and Human Services (HHS).
3. Patient co-payments under third party Medicare and private reimbursement programs are affordable.
4. The geographic area for the exclusivity excludes countries with a per capita income less than 30 percent that of the United States, and, if there is no such exclusion, the company be required to report annually on the reasonable and feasible measures that will be taken to ensure access to patients living in such countries. Here, please note the data from <http://drugdatabase.info/drug-prices/>, which shows that in many developing countries, prices are frequently higher than the prices for high income countries in Europe, despite the much lower per capita income in developing countries (including for taxpayer funded cancer drugs), illustrating the need for a policy to be included in NIH licenses.
5. The initial period of exclusivity is set at seven years, subject to extensions if the company can demonstrate it has not recovered sufficient profits given the risk-adjusted value of the clinical trials used to register similar drugs for the lead indication.
6. Absent satisfaction of the requirements of proposed safeguard number 5, the exclusivity of the product be reduced when cumulative global revenues for the product exceed \$1 billion, by one year for every \$0.5 billion in cumulative sales that exceed \$1 billion in cumulative sales.

Note that the licensing of inventions to the company significantly reduces the company's costs of preclinical research, which various studies have estimated to be 40 to 55 percent of drug development costs on a risk- and capital cost-adjusted basis.

To address research by third parties on the patented invention, we propose the NIH explicitly permit researchers worldwide to use the inventions for research purposes, regardless of whether or not research has a grant or contract from a U.S. government agency, and for both profit or non-profit organizations.

To address transparency, we proposes the following requirements.

The company will be required to provide an annual report for the public providing disclosures of the following items:

1. The amount of money R&D to obtain FDA and foreign government approvals of the inventions, including in particular, the amount of money spent each year on each trial, and the relevant tax credits, grants and other subsidies received from any government or charity relating to those R&D outlays,
2. The prices and revenue for the products, by country,
3. The number of units sold, in each country,
4. The product-relevant patents obtained in each country, and
5. The regulatory approval obtained in each country.

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,
twitter.com/jamie_love

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,
twitter.com/jamie_love

From: James Love [james.love@keionline.org]
Sent: 7/16/2018 8:37:11 PM
To: Greene, Jaime (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e06e39f0bcd34511a92df20c5dc8722a-greenejaime]
Subject: Re: Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Hematological Cancers. Notice for comment published in 83 FR 22501
Attachments: morphiex.com.png

Is the company web page Morphix.com or Morphix.com?

These are different names, is it the same company?

On Mon, Jul 16, 2018 at 4:12 PM, Greene, Jaime (NIH/NCI) [E] <greenejaime@mail.nih.gov> wrote:

Dear Mr. Love,

Thank you for your comments with regard to the Notice of Prospective Grant of an Exclusive License to Morphix Biotherapeutics for NIH technology reference no. E-227-2006.

We have considered your comments and provide the attached response.

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Jaime

Jaime Meredith Greene, M.S.
Senior Technology Transfer Manager

NCI Technology Transfer Center

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From: James Love [mailto:james.love@keionline.org]
Sent: Thursday, May 31, 2018 11:29 AM
To: Greene, Jaime (NIH/NCI) [E] <greenejaime@mail.nih.gov>
Subject: Morphix license

Dear Jaime Greene,
I believe this mail bounced for some reason yesterday.
Jamie

Jaime M. Greene
Senior Licensing and Patenting Manager
NCI Technology Transfer Center
Email: greenejaime@mail.nih.gov.
Date: May 30, 2018

Re: Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Hematological Cancers. Notice for comment published in 83 FR 22501.

REL0000024833.0005

Dear Jaime Greene:

Knowledge Ecology International (KEI), HealthGap and the Union for Affordable Cancer Treatment (UACT) are organizations concerned about drug pricing and access to patented medicines, offering comments on the grant of an exclusive license of the National Institutes of Health (NIH) patents noticed in [83 FR 22501](#), to Morphix Biotherapeutics (“Morphix”) located in Boston, MA. The above entities oppose the issuing of the license unless:

- A. The NIH has determined that an exclusive license is “a reasonable and necessary incentive” to induce investments for the development and practical application of the invention, as is required by 35 USC § 209, and shares its analysis with the public; and
- B. The NIH limits the scope of rights for the exclusivity to only those rights reasonably necessary to induce investments for the development and practical application of the invention, and in particular, that the field of use is sufficiently narrow, that the term of the exclusivity is sufficiently limited, and that the license contains sufficient safeguards to ensure that the invention is “available to the public on reasonable terms,” as is required by 35 USC § 209 and 35 USC § 201(f).

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Our comments address three areas of concern, (1) the pricing, affordability and access issues, (2) freedom for researchers to use the inventions, and (3) requirements for transparency of the development and commercialization of the medicine.

We propose the following safeguards regarding the pricing of and access to products that use the inventions:

1. Products are priced no higher in the United States than the median price charged in the seven largest economies as measured by nominal GNI that have a nominal GNI per capita of at least 50 percent of the United States. To fully appreciate our concerns about the discriminatory pricing that makes US residents pay more than everyone else, please review the cross country price comparisons here: <http://drugdatabase.info/drug-prices/>
2. Prices for products in the United States do not exceed the estimated value of the treatment, as determined by independent health technology assessments selected by Department of Health and Human Services (HHS).
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Note that the licensing of inventions to the company significantly reduces the company’s costs of preclinical research, which various studies have estimated to be 40 to 55 percent of drug development costs on a risk- and capital cost-adjusted basis.

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2. The prices and revenue for the products, by country,
3. The number of units sold, in each country,
4. The product-relevant patents obtained in each country, and
5. The regulatory approval obtained in each country.

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James Love. Knowledge Ecology International
<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,
twitter.com/jamie_love

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James Love. Knowledge Ecology International
<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,
twitter.com/jamie_love



This site can't be reached

www.morpheix.com's server IP address could not be found.

- Did you mean <http://www.morphix.com/>?
- Search Google for morphix

ERR_NAME_NOT_RESOLVED

From: Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]
Sent: 7/8/2019 1:28:14 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Pazman, Cecilia (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf35741501e247d887acd224eaf9d679-pazmance]
Subject: FW: 84 FR 28063, Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors, to Molecular Targeting Technologies, Inc. (MTTI)
Attachments: NIH to KEI re MTTI amendment 8 July 2019.pdf

From: Shmilovich, Michael (NIH/NHLBI) [E]
Sent: Monday, July 8, 2019 9:28 AM
To: Luis Gil Abinader <luis.gil.abinader@keionline.org>; 'James Love' <james.love@keionline.org>; Manon Ress <MANON.RESS@cancerunion.org>; kathryn.ardizzone@keionline.org
Subject: 84 FR 28063, Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors, to Molecular Targeting Technologies, Inc. (MTTI)

Dear KEI and Cancer Union—

Thank you for your comments. NIH's response enclosed.

Michael A. Shmilovich, Esq., CLP



National Heart, Lung,
and Blood Institute

Office of Technology Transfer and Development
31 Center Drive Room 4A29, MSC2479
Bethesda, MD 20892-2479
o. 301.435.5019
shmilovm@mail.nih.gov

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"Always be yourself....unless you can be a pyrate... then; obviously, be a pyrate"

REL0000024834



National Heart, Lung,
and Blood Institute

Office of Technology Transfer and Development
31 Center Drive Room 4A29, MSC2479
Bethesda, MD 20892-2479
Michael Shmilovich, Esq., CLP
shmilovm@mail.nih.gov

July 8, 2019

Knowledge Ecology International (KEI)
Kathryn Ardizzone, Esq.
James Love
Manon Ress
Luis Gil Abinader
Knowledge Economy International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009

IN RE: 84 FR 28063, Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors, to Molecular Targeting Technologies, Inc. (MTTI).

Dear Ms. Ardizzone, Mr. Love, Ms. Ress, and Mr. Abinader:

Thank you for providing us with your comments regarding the aforementioned Federal Register notice.

Prior to posting notices of a proposed grant of exclusive commercialization licenses, the NIH determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company applying is qualified both technically and financially to be granted an exclusive license to the Government's intellectual property in the field specified. The notice period provides an opportunity for public comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license. We reviewed your comments pertaining to applicable federal statutes regulations, and pricing and will take them into consideration. With regards to your comments regarding clinical trials NCT0330868213 and NCT03478358, those are small scale first-in-patient trials and are unrelated to trials that MTTI may conduct in furtherance of their commercialization efforts.

If your organization requests more documentation, such requests should be filed under the Freedom of Information Act. The webpage for the NIH FOIA Office provides more information on filing requests <http://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests>.

Sincerely,

b6

Michael A. Shmilovich, Esq., CLP

REL0000024834.0001

From: Ahsan, Sidra (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E35C4D5FD1054799828811EBE4187A59-AHSANS]
Sent: 6/18/2019 6:01:25 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Discuss objection to FRN [A-161-2018]
Attachments: NIH Response Letter 84 FR 23798_updated.docx

Hi Mark

I have added the sentence. Please see final attached.

Best
Sidra

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, June 18, 2019 12:56 PM
To: Ahsan, Sidra (NIH/NCI) [E] <sidra.ahsan@nih.gov>
Subject: RE: Discuss objection to FRN [A-161-2018]

Could you say ..."we will give your comments and suggestions serious consideration"

Please send me a copy of the final response to KEI. Thanks

From: Ahsan, Sidra (NIH/NCI) [E] <sidra.ahsan@nih.gov>
Sent: Tuesday, June 18, 2019 12:34 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: RE: Discuss objection to FRN [A-161-2018]

Hi Mark

Please review the attached response to KEI objection, as discussed on the call this afternoon.

Thanks
Sidra
240-276-6468

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, June 18, 2019 11:47 AM
To: Ahsan, Sidra (NIH/NCI) [E] <sidra.ahsan@nih.gov>
Subject: RE: Discuss objection to FRN [A-161-2018]

Can you call me before 12:30 or after 4:15? 301-435-4485

From: Ahsan, Sidra (NIH/NCI) [E] <sidra.ahsan@nih.gov>
Sent: Tuesday, June 18, 2019 10:45 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: Discuss objection to FRN [A-161-2018]

Hi Mark

We received an objection to an FRN from KEI (see attached). This is a co-owned technology and the prospective licensee is one of the owners of the technology. FRN available here: <https://www.federalregister.gov/documents/2019/05/23/2019-10779/prospective-grant-of-an-exclusive-patent-license-the-development-and-use-of-a-therapeutic-stat3>.

I would like to discuss this specific case with you. Please let me know if you are available any time today or this week.

Thanks

Sidra Ahsan, Ph.D., Patent Agent
Technology Transfer Manager
Technology Transfer Center
National Cancer Institute, National Institutes of Health
9609 Medical Center Drive, Rm 1E530
Bethesda, MD 20892-9702 (for business mail)
Rockville, MD 20850-9702 (for courier service/visitors)
Phone : 240-276-6468
Fax 240-276-5504
sidra.ahsan@nih.gov
<https://ttc.nci.nih.gov>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health/ NCI
9609 Medical Center Drive, Suite 530
Rockville, MD 20852
Office (240) 276-5530
Facsimile (240) 276-5504

b5

From: Knabb, Jim (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=535517D229E04963A2B928742CB80DA0-KNABBJR]
Sent: 4/18/2019 7:47:28 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]
Subject: FW: Inquiry regarding FR 2019-06575 - Proposed Exclusive License on CART therapies for FMS-like tyrosine kinase 3 Expressing Cancers

Hi Mark,

I have a FRN expiring tomorrow and received a second set of questions from KEI. Some of these seem broader than this specific grant of rights, so I wanted to touch base with you as to which of these questions needed to be addressed.

Appreciate your help on this, happy to discuss at your convenience.

Jim

From: Claire Cassedy <claire.cassedy@keionline.org>
Sent: Thursday, April 18, 2019 10:57 AM
To: Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>
Subject: Re: Inquiry regarding FR 2019-06575 - Proposed Exclusive License on CART therapies for FMS-like tyrosine kinase 3 Expressing Cancers

Dear Jim,

Thank you for your previous responses. I wanted to follow up with a few more questions regarding this proposed license:

1. The body of this notice refers to this as an "Exclusive/Co-exclusive License," but only lists Senti Bio as a licensee. Who is the co-licensee for the co-exclusively licensed technology?
2. In preparing to license this technology, did the NIH conduct an analysis of the market value of current CAR T technologies when determining how to set royalties in this license?
3. If the license is executed, will the government follow with any subsidies or funding of clinical trials related to the listed inventions in the Patents and Patent Applications section of the notice?
4. Can you provide us with information on the budget of NIH-funded clinical trials on the CAR T technologies licensed to Gilead/Kite Pharma by the NIH, referenced in [82 FR 60406](#)? This information speaks to the question of the scope of rights on the contract.
5. Can you provide us with information regarding any of the clinical trial for CAR T-related technologies for which the NIH is providing funding? We note that there are more than 40 trials listed on Clinicaltrials.gov related to CAR T that list the NIH as a funder.

Thank you in advance for your assistance and please let me know if you need any clarification regarding these questions.

Best Regards,
Claire

—
Claire Cassedy
Knowledge Ecology International

REL0000024836

On Fri, Apr 5, 2019 at 11:15 AM Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov> wrote:

Dear Claire,

Many thanks for your comments and questions related to this proposed grant of an exclusive license to Senti Biosciences.

To address the questions you lay out below:

This technology is at the preclinical stage of development, and the government has not funded any clinical trials relevant to this technology.

Please let me know if you have any follow up questions.

Best Regards,

Jim

From: Claire Cassedy <claire.cassedy@keionline.org>

Sent: Wednesday, April 3, 2019 10:42 AM

To: Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>

Subject: Inquiry regarding FR 2019-06575 - Proposed Exclusive License on CART therapies for FMS-like tyrosine kinase 3 Expressing Cancers

Dear Mr. Knabb,

I am writing in reference to the Federal Register notice (FR 2019-06575) regarding, "Prospective Grant of an Exclusive/Co-Exclusive Patent License: Development and Commercialization of Next Generation Chimeric Antigen Receptor Therapies for the Treatment of FMS-like tyrosine kinase 3 Expressing Cancers," for which you are listed as the contact for inquiries. I was hoping you could provide me with some further information regarding the status of the technologies.

1. At what stage of development are the inventions listed?
2. Has the government funded any clinical trials relevant to these technologies?
3. If the government has provided funding, how much has been spent by the government on these trials? Can you provide NCT numbers?

Thank you in advance for your assistance in this matter.

Best Regards,

Claire Cassidy

--

Claire Cassidy

Knowledge Ecology International

1621 Connecticut Avenue NW

Suite 500

Washington, DC 20009

Tel.: 1.202.332.2670

From: Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]
Sent: 12/5/2019 6:42:19 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Deutsch, Mary Frances (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dfd60551fcc40ff8ca4caa248f73d94-deutschm]
Subject: RE: NIH FOIA Request for Direct - Ardizzone - FW: Request under the Freedom of Information Act (#52953)

Mark: We think this is the 3rd similar request from KEI. As soon as we can recover earlier responses to KEI, I will let you know what we provided before which should be similar to what we will provide for this new request. I think we

b5

Will have more information for you by Monday.

Ann

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Thursday, December 5, 2019 1:39 PM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Cc: Deutsch, Mary Frances (NIH/OD) [E] <deutschm@od.nih.gov>
Subject: Re: NIH FOIA Request for Direct - Ardizzone - FW: Request under the Freedom of Information Act (#52953)

What aspect of the waiver requests are you providing?

Sent from my iPhone

On Dec 5, 2019, at 12:20 PM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:

From: Hammersla, Ann (NIH/OD) [E]
Sent: Thursday, December 5, 2019 12:20 PM
To: Brandy, Aesha (NIH/OD) [C] <aesha.brandy@nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Subject: RE: NIH FOIA Request for Direct - Ardizzone - FW: Request under the Freedom of Information Act (#52953)

Aesha:

DEITR has the requested information for only US Manufacturing waiver requests submitted to NIH by NIH's extramural funding recipients. DEITR does not have information concerning waiver requests for NIH's intramural research program. If OTT does not have the information on intramural US Manufacturing requests, perhaps Mark Rohrbaugh would know where the data is kept.

Also, KEI may have requested and been provided with similar information concerning NIH's extramural US manufacturing requests several years ago. DEITR will provide the information requested for US Manufacturing requests made by NIH's extramural funding recipients.

Ann

REL0000024837

From: Brandy, Aesha (NIH/OD) [C] <aesha.brandy@nih.gov>
Sent: Thursday, December 5, 2019 12:05 PM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Subject: FW: NIH FOIA Request for Direct - Ardizzone - FW: Request under the Freedom of Information Act (#52953)

Hi Ann –

Please see the FOIA request below which OTT states the information is housed within OER. Are you able provide these documents? Please let me know if this should be forwarded to another SME for response.

Thanks so much.

Best,
Aesha

From: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>
Sent: Wednesday, September 25, 2019 9:35 AM
To: NIH FOIA <nihfia@od.nih.gov>
Subject: RE: Request under the Freedom of Information Act

Good morning,

The office of Extramural Research (OER) is the office of record.
I handled waiver recommendations to OER from 2005 to 2014.
OER however made the final decision and sent all responses to the requesters.
They would have records of all final determinations during the requested period.

Gina

From: NIH FOIA <nihfia@od.nih.gov>
Sent: Tuesday, September 24, 2019 2:11 PM
To: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>
Subject: FW: Request under the Freedom of Information Act

Hi Gina,

Does NIH/OTT maintain any records of “US manufacturing requirement waiver requests and determinations”?

Thanks Gina.

- Roger

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Tuesday, September 24, 2019 2:08 PM
To: NIH FOIA <nihfia@od.nih.gov>
Cc: James Love <james.love@keionline.org>; Claire Cassedy <claire.cassedy@keionline.org>; kei-foia-request@keionline.org
Subject: Request under the Freedom of Information Act

REL0000024837

Dear Sir or Madam:

On behalf of Knowledge Ecology International (KEI), I am submitting the attached FOIA request for an electronic copy of all NIH U.S. manufacturing requirement waiver requests and determinations, from 2009 to present.

Thank you in advance for processing the attached request.

Sincerely,

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From: James Love [james.love@keionline.org]
Sent: 12/20/2019 7:25:06 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Kathryn Ardizzone [kathryn.ardizzone@keionline.org]
Subject: Clare Love

Mark,

Regarding your letter of November 26, 2019. Clare Love is a man, not a woman. He is a 77 year old, Viet Nam Vet, who has had cancer twice, once for lymphoma, now in remission, and more recently prostate cancer. He is not an employee of KEI.

I thought I would also note that Knowledge Ecology International (KEI), Union for Affordable Cancer Treatment (UACT), Public Citizen, Social Security Works (SSW), LWC Health, Ruth Lopert, Manon Ress, and Terry Love were among those involved in the appeal.

Jamie

--

James Love. Knowledge Ecology International
U.S. Mobile +1.202.361.3040
U.S. office phone +1.202.332.2670
<http://www.keionline.org>
twitter.com/jamie_love

From: Bigelow, Bill (NIH/OD) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C2C6754ACEC1498DB336E6DCDDBBDE89-BIGELOWWS]
Sent: 12/17/2018 3:55:47 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Leahy, Timothy (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0dd68edc3c0547a8aff240eb895a9ace-leahyt]; Finley, Stephen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=884c93801ba445f68c2ba0ce4913f3c8-finleys]; Bill Bigelow [bbigelow@sapient.com]
Subject: RE: searching [b5]
Attachments: KEl [b5]

Good Morning Mark,

I was able to do a universal search of [b5]

[b5]

Unfortunately, [b5]

[b5]

I have attached a zip folder that contains the downloaded [b5] Please let us know if this is enough to get you what you need.

Thank you,
Bill

BILL BIGELOW



National Institutes of Health
Office of Intramural Research
Office of Technology Transfer

6011 Executive Blvd., Rm. 325
Rockville, MD 20852-3804
Phone: (301) 594-4697
Fax: (301) 402-0220
Email: bill.bigelow@nih.gov

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Friday, December 14, 2018 3:51 PM
To: Finley, Stephen (NIH/OD) [E] <finleys@od6100m1.od.nih.gov>; Leahy, Timothy (NIH/OD) [E] <leahyt@od.nih.gov>
Subject: RE: searching [b5]

By Wednesday. If it is a tough lift, just let me know. It might be easier to just look at [b5]

[b5]

You could try [b5]

[b5]

Thanks

From: Finley, Stephen (NIH/OD) [E] <finleys@od6100m1.od.nih.gov>
Sent: Friday, December 14, 2018 3:44 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: RE: searching [b5]

REL0000024840

Tim
Not really sure. The [REDACTED] b5 I suspect
that [REDACTED] b5

Regardless, it will be a tough assignment to complete

Stephen

Stephen L. Finley, Ph.D.
NIH Office of Technology Transfer
Senior Advisor
Email: sf31w@nih.gov

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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Friday, December 14, 2018 2:51 PM
To: Leahy, Timothy (NIH/OD) [E] <leahyt@od.nih.gov>; Finley, Stephen (NIH/OD) [E] <finleys@od6100m1.od.nih.gov>
Subject: searching [REDACTED] b5

Tim and Steve:

I am working on something for OGC and would like to [REDACTED] b5
[REDACTED] b5 Is there a way to search [REDACTED] b5

Thanks

Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer
Director, Division of Technology Transfer and Innovation Policy
Office of Science Policy
Office of the Director
National Institutes of Health

REL0000024840

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From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 12/20/2019 10:13:20 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Request for an Extension Regarding Response to NIH's November 26, 2019 Letter

Looks good

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Friday, December 20, 2019 5:05 PM
To: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Cc: James Love <james.love@keionline.org>
Subject: RE: Request for an Extension Regarding Response to NIH's November 26, 2019 Letter

Dear Ms. Ardizzone:

In my letter to KEI on November 26 under "Standing" (pages 7 and 8), I explained that NIH determined KEI could not be damaged and lacked standing under 404.11. Accordingly, there is no appeal available, and the deadline under 404.11 is thus not applicable.

Regards,

Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer
Office of Science Policy
National Institutes of Health

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Friday, December 20, 2019 3:43 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: James Love <james.love@keionline.org>
Subject: Request for an Extension Regarding Response to NIH's November 26, 2019 Letter

Dear Dr. Rohrbaugh:

Please let me know if you would be willing to extend the time to respond to the NIH's November 26, 2019 letter addressing two appeals recently submitted by KEI and other public interested groups and concerned individuals.

I just returned to work, [b6] leave and would greatly appreciate additional time to review the letter, coordinate with the other groups/individuals involved, and formulate a response, if we decide to do so.

Also, per the NIH's appeals procedures, if we decide to submit a second-level appeal, it would be due December 26, 2019 - the day after Christmas, and many of the individuals and groups with which we submitted the original letters have already begun their holiday leave.

Submitting a response to your letter by December 26, 2019 would be difficult under these circumstances, and a 15-day extension would be greatly appreciated.

REL0000024843

Thank you in advance for considering this request for an extension.

Sincerely,

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From: Surabian, Karen (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=604A0E2013504631921434A90B327010-SURABIANK_1]
Sent: 7/9/2018 8:55:03 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Prospective grant of an exclusive license

Karen T. Surabian
Licensing and Patenting Manager
CDC Team
Technology Transfer and Intellectual Property Office (TTIPO)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
5601 Fishers Lane, Rm. 2G48, MSC 9804
Rockville, MD 20892

Phone: [+1-301-594-9719](tel:+1-301-594-9719)
Email: karen.surabian@nih.gov

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From: Surabian, Karen (NIH/NIAID) [E]
Sent: Monday, July 9, 2018 3:41 PM
To: 'james.love@keionline.org' <james.love@keionline.org>
Subject: Prospective grant of an exclusive license

Dear Mr. Love,

Thank you for your emails dated Monday, June 18, 2018 and Monday, July 02, 2018 regarding the prospective grant of an exclusive license to the University of Liverpool, published in the Federal Register on June 15, 2018 (Volume 83, Number 116, Pages 28002-28003).

Prior to posting this notice, NIAID reviewed the business development plan provided by the license applicant, as well as other relevant information, and determined that the prospective license meets the requirements of 35 USC §209 and 37 CFR Part 404. We have also considered all comments received in response to the notice before determining whether to proceed with negotiation of the proposed license. In particular, we have carefully reviewed and given serious consideration to the comments provided by KEI. We have determined that KEI's comments fail to establish that the grant of the prospective license to the University of Liverpool would be inconsistent with applicable regulatory and statutory requirements. Accordingly, NIAID intends to proceed with negotiation of an exclusive license to the University of Liverpool. NIAID has adhered to all regulations and statutes pertaining to the grant of an exclusive license during its evaluation of this prospective license.

REL0000024844

As the field of use of the prospective license is limited to therapeutics, other fields of use for these intellectual property rights remain available; for example, use of the P4 peptide in research applications or in diagnostic assays. NIAID will seek other licensees to develop the available fields of use.

Regarding your questions, we are unable to provide information pertaining to the applicant's business development plan as it is privileged and confidential and is not subject to disclosure under 5 USC §552.

Sincerely,
Karen Surabian

Karen T. Surabian
Licensing and Patenting Manager
CDC Team
Technology Transfer and Intellectual Property Office (TTIPO)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
5601 Fishers Lane, Rm. 2G48, MSC 9804
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Email: karen.surabian@nih.gov

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From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 12/20/2019 9:53:17 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Request for an Extension Regarding Response to NIH's November 26, 2019 Letter

b5

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Friday, December 20, 2019 4:51 PM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: RE: Request for an Extension Regarding Response to NIH's November 26, 2019 Letter

What should the response be.

b5

b5

From: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Sent: Friday, December 20, 2019 4:48 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: RE: Request for an Extension Regarding Response to NIH's November 26, 2019 Letter

b5

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Friday, December 20, 2019 4:43 PM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: RE: Request for an Extension Regarding Response to NIH's November 26, 2019 Letter

b5

From: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Sent: Friday, December 20, 2019 4:41 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: RE: Request for an Extension Regarding Response to NIH's November 26, 2019 Letter

b5

I'm looking now.

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Friday, December 20, 2019 4:06 PM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: FW: Request for an Extension Regarding Response to NIH's November 26, 2019 Letter

Shall I tell them

b5

REL0000024845

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Friday, December 20, 2019 3:43 PM

To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>

Cc: James Love <james.love@keionline.org>

Subject: Request for an Extension Regarding Response to NIH's November 26, 2019 Letter

Dear Dr. Rohrbaugh:

Please let me know if you would be willing to extend the time to respond to the NIH's November 26, 2019 letter addressing two appeals recently submitted by KEI and other public interested groups and concerned individuals.

I just returned to work, on a part time basis, from maternity leave and would greatly appreciate additional time to review the letter, coordinate with the other groups/individuals involved, and formulate a response, if we decide to do so.

Also, per the NIH's appeals procedures, if we decide to submit a second-level appeal, it would be due December 26, 2019 - the day after Christmas, and many of the individuals and groups with which we submitted the original letters have already begun their holiday leave.

Submitting a response to your letter by December 26, 2019 would be difficult under these circumstances, and a 15-day extension would be greatly appreciated.

Thank you in advance for considering this request for an extension.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

From: Knabb, Jim (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=535517D229E04963A2B928742CB80DA0-KNABBJR]
Sent: 4/18/2019 8:04:28 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Senti Bio ("Senti") license

From: James Love <james.love@keionline.org>
Sent: Friday, April 12, 2019 4:31 AM
To: Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>
Subject: Senti Bio ("Senti") license

Dear Jim Knabb,

Would the NIH be open to including an option for non-exclusive licensing in countries that demonstrate the capacity to provide CAR T cell modification and manufacturing, such as a country in Europe that is part of the European Patent Convention, that wanted to develop domestic capacity in this area.

Jamie

--

James Love. Knowledge Ecology International
U.S. Mobile +1.202.361.3040
U.S. office phone +1.202.332.2670
<http://www.keionline.org>
twitter.com/jamie_love

From: James Love [james.love@keionline.org]
Sent: 12/21/2019 9:30:03 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: kathryn ardizzone [kathryn.ardizzone@keionline.org]
Subject: Re: Request for an Extension Regarding Response to NIH's November 26, 2019 Letter

Mark, are you saying that KEI and the other groups and individuals have exhausted their administrative appeals for both cases?

Jamie

On Fri, Dec 20, 2019 at 5:05 PM Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov> wrote:

Dear Ms. Ardizzone:

In my letter to KEI on November 26 under “Standing” (pages 7 and 8), I explained that NIH determined KEI could not be damaged and lacked standing under 404.11. Accordingly, there is no appeal available, and the deadline under 404.11 is thus not applicable.

Regards,

Mark L. Rohrbaugh, Ph.D., J.D.

Special Advisor for Technology Transfer

Office of Science Policy

National Institutes of Health

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Friday, December 20, 2019 3:43 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: James Love <james.love@keionline.org>
Subject: Request for an Extension Regarding Response to NIH's November 26, 2019 Letter

Dear Dr. Rohrbaugh:

Please let me know if you would be willing to extend the time to respond to the NIH's November 26, 2019 letter addressing two appeals recently submitted by KEI and other public interested groups and concerned individuals.

I just returned to work, on a part time basis, from maternity leave and would greatly appreciate additional time to review the letter, coordinate with the other groups/individuals involved, and formulate a response, if we decide to do so.

Also, per the NIH's appeals procedures, if we decide to submit a second-level appeal, it would be due December 26, 2019 - the day after Christmas, and many of the individuals and groups with which we submitted the original letters have already begun their holiday leave.

Submitting a response to your letter by December 26, 2019 would be difficult under these circumstances, and a 15-day extension would be greatly appreciated.

Thank you in advance for considering this request for an extension.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

--

James Love. Knowledge Ecology International
U.S. Mobile +1.202.361.3040
U.S. office phone +1.202.332.2670
<http://www.keionline.org>
twitter.com/jamie_love

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 3/11/2019 3:54:20 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Response to KEI Objection
Attachments: Response to KEI J Love Comments_draft 3-11-19.docx

Thanks, Mark.

I made some edits in view of your comments. Could you take a last look before this goes out?

Thanks again,

Andy

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Friday, March 8, 2019 4:45 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Subject: Re: Response to KEI Objection

For sec 209, I think

b5

b5

Sent from my iPhone

On Mar 8, 2019, at 7:56 AM, Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Hi Mark,

I've prepared a response to KEI's objection to my recent FR notice. Please take a look and let me know if you have any edits, concerns, etc. For reference, I've also provided a copy of the objection and a link to the FR notice itself.

Thank you,

Andy

FR Notice: <https://www.federalregister.gov/documents/2019/02/07/2019-01431/prospective-grant-of-an-exclusive-patent-license-development-and-commercialization-of-cell-therapies>

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, March 7, 2019 11:06 AM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Subject: RE: Response to KEI Objection

Dale suggests

b5

b5

REL0000024848

From: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Sent: Thursday, March 07, 2019 10:36 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: RE: Response to KEI Objection

Hi Mark,

Could you send me the language you referenced yesterday?

Thanks,

Andy

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, March 6, 2019 11:04 AM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Subject: Re: Response to KEI Objection

[REDACTED] b5
[REDACTED] b5 I will send it to you.

Sent from my iPhone

On Mar 6, 2019, at 10:51 AM, Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Hi Mark,

I'm in the process of drafting a reply to KEI's objection to my recent FR notice. As before, they reference the following:

"Before the NIH grants a new or expanded license to Ziopharm Oncology, Inc., we expect the NIH to seek the advice of the Department of Justice antitrust authorities, as is required by 40 U.S. Code § 559 - Advice of Attorney General with respect to antitrust law."

Do you know if [REDACTED] b5
[REDACTED] b5

Thank you,

Andy

Andrew R. Burke, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute
9609 Medical Center Drive, Rm 1E550
Rockville, MD 20850

Direct: (240) 276-5484
Email: andy.burke@nih.gov

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<2019 Ziopharm Oncology Inc. license NIH February 22 2019 autologus T Cell.pdf>

<Response to KEI J Love Comments_draft 3-5-19.docx>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health/ NCI
9609 Medical Center Drive, Suite 530
Rockville, MD 20852
Office (240) 276-5530
Facsimile (240) 276-5504

b5

Sincerely,

Andrew Burke, Ph.D.
Senior Technology Transfer Manager

From: kathryn ardizzone [kathryn.ardizzone@keionline.org]
Sent: 12/24/2019 12:30:07 AM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: James Love [james.love@keionline.org]
Subject: Re: Request for an Extension Regarding Response to NIH's November 26, 2019 Letter

Dear Dr. Rohrbaugh:

Thank you for explaining the NIH's position regarding KEI's desire to proceed with the second-stage of an appeal concerning the NIH's November 26, 2019 letter. Because you have indicated that no further appeal is available, we will interpret the NIH's November 26, 2019 letter as the NIH's final agency determination for the purposes of exhaustion of administrative remedies and judicial review.

Sincerely,
Kathryn Ardizzone

On Fri, Dec 20, 2019 at 5:05 PM Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov> wrote:

Dear Ms. Ardizzone:

In my letter to KEI on November 26 under "Standing" (pages 7 and 8), I explained that NIH determined KEI could not be damaged and lacked standing under 404.11. Accordingly, there is no appeal available, and the deadline under 404.11 is thus not applicable.

Regards,

Mark L. Rohrbaugh, Ph.D., J.D.

Special Advisor for Technology Transfer

Office of Science Policy

National Institutes of Health

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Friday, December 20, 2019 3:43 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: James Love <james.love@keionline.org>
Subject: Request for an Extension Regarding Response to NIH's November 26, 2019 Letter

Dear Dr. Rohrbaugh:

Please let me know if you would be willing to extend the time to respond to the NIH's November 26, 2019 letter addressing two appeals recently submitted by KEI and other public interested groups and concerned individuals.

I just returned to work, on a part time basis, from maternity leave and would greatly appreciate additional time to review the letter, coordinate with the other groups/individuals involved, and formulate a response, if we decide to do so.

Also, per the NIH's appeals procedures, if we decide to submit a second-level appeal, it would be due December 26, 2019 - the day after Christmas, and many of the individuals and groups with which we submitted the original letters have already begun their holiday leave.

Submitting a response to your letter by December 26, 2019 would be difficult under these circumstances, and a 15-day extension would be greatly appreciated.

Thank you in advance for considering this request for an extension.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

--

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(301) 496-9839 (Fax)
<http://osp.od.nih.gov/index.html>

November 26, 2019

Knowledge Ecology International
1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009

Via email: kathryn.ardizzone@keionline.org

Re: (1) Exclusive license in bicistronic chimeric antigen receptor (CAR) constructs targeting CD19 and CD20 to Kite Pharma, Inc., described in Federal Register Notices 84 FR 33270 and 33272.
(2) Exclusive license in genetically-modified lymphocytes for cancer therapy to Intima Bioscience, Inc., described in Federal Register Notice 84 FR 45503

Dear Knowledge Ecology International:

Thank you for your letters of September 13 and October 26, 2019 regarding the proposed licenses referenced above. Several of the issues you raised in your letters are shared by the two matters, and I will attempt to address each of them below

(1) License in bicistronic chimeric antigen receptor (CAR) constructs to Kite Pharma, Inc.

In your letter of September 13, 2019, you raised six issues with respect to this proposed exclusive license.

1. Did the NIH properly evaluate the necessity of granting an exclusive license in the subject inventions as required by statute.

You suggest that the NIH did not properly evaluate the necessity of granting an exclusive license to Kite Pharma, Inc. ("Kite") for the bicistronic CAR constructs ("the constructs"). This is because you believe that NIH did not consider FDA regulatory protection of test data and orphan drug exclusivity of two other products, Yescarta and Kymriah, marketed by Kite and Novartis, respectively.

NIH is aware of the role of regulatory protection in preserving market space for its licensees, but these are only part of the exclusivity necessary for a company like Kite to risk technology failure and the enormous investment necessary to bring therapies to market. As you know, these cutting-edge therapies have the potential to extend the lives of patients significantly and, in some cases, even offer a complete cure. However, they are still largely experimental and hundreds of millions of dollars are typically necessary to conduct the clinical trials required to obtain regulatory approval and bring them to market. The likelihood that any one therapy will reach the market is small. The costs and risks are even higher for these trials and therapies because of the complex methods required to process the therapeutic cells and introduce them back into the patient concurrent with hospitalization and treatment of ill effects of the therapy.

Missing in your analysis is that the National Institutes of Health (“NIH”), like any other licensor of technology, works in a market for these early-stage therapeutic technologies in which there is essentially no demand for nonexclusive licenses. This is unlike other markets, for example diagnostics, in which nonexclusive licensing may be the norm. NIH has no authority to commercialize the technologies itself, and so it partners with companies assessed to be most capable of bringing therapies to patients as quickly as possible. NIH exclusive license agreements include benchmarks and milestones that preserve NIH’s right to pull back the license if the licensee fails to make adequate progress in bringing the therapy to patients. NIH determined that granting an exclusive license to this technology was necessary to “promote the commercialization and public availability”¹ of the technology as called for by the Bayh-Dole Act, while including terms in the license agreement to assure that no part of the invention remains untried or under developed.

2. Did NIH meet its statutory responsibility to limit the scope of rights to that which is reasonably necessary to induce investment to bring the invention to practical application?

You argue further in your letter that NIH did not meet its statutory responsibility to limit the scope of rights to that which is reasonably necessary to induce the investment required to bring the invention to practical application. That statement is not supported by the facts. The Federal Register Notice (“FRN”) in which the proposed license is noticed recites that the license will be limited to:

The development, production and commercialization of an anti-CD19 anti-CD20 dual targeting chimeric antigen receptor (CAR)-based immunotherapy using autologous (meaning one individual is both the donor and the recipient) immune cells transfected with either a viral or non-viral vector, wherein the vector expresses a CAR having at least: (1) A dual antigen specificity; (2) the complementary determining region (CDR) sequences of the anti-CD19 antibody known as Hu19; (3) the complementary determining region (CDR) sequences of the anti-CD20 antibody known as 2.1.2; and (4) a T cell signaling domain; for the treatment of B-cell derived human cancers.

¹ 35 U.S.C. § 200.

The FRN further recites that Non-Hodgkin Lymphoma (NHL), acute lymphoblastic leukemia (ALL) and chronic lymphocytic leukemia (CLL) might be treated using this technology. The fields of use granted in NIH license agreements must be supported by the licensee's detailed commercialization plan for each disease indication. A pull-back clause permits NIH to withdraw any field of use not being developed by the licensee and provide those rights to another company. Consequently, no field of use will lie fallow. Each indication to which the licensee can commit its resources improves the chances of success for the other indications it has licensed, since the licensee's motivation is driven by its overall chance of success.

The scope of treatment approaches using this technology is effectively limited by the scope of the patent claims involving the CDR sequence limitations. Changing one amino acid in any of 12 different sequences could move such an approach outside the patent claims. NIH is thus aware of its responsibility to tailor the scope of rights as reasonably necessary to induce investment and make the technology available to the public, and it has done so in the case of these CAR constructs.

You also note that the term of the exclusive license should be shorter. NIH and recipients of NIH funding normally grant exclusive commercial licenses for the life of the patents. Prior to June 1995, several decades could pass before all the patents in a family expired 17 years from each of the succeeding issue dates, initially an unknown time period. The term of patents in a given family could have run for several decades following the initial application filing.

Patent families now have clearly defined, limited terms of 20 years from the initial filing date, regardless of the time needed to bring the related patent applications to issuance. After many years of development to reach FDA approval, the remaining patent term for a marketed product is a fraction of the entire patent term. Depending on the product, the regulatory exclusivity granted at the time of FDA marketing approval may run for a longer period than the remaining patent term. Given these risks, companies are not willing to develop products from very early stage technologies without a license for the term of the patent. It is quite rare in the drug and therapeutic field that NIH would not have licensed a patent covering a product already on the market, in which case a company would have no choice but to take a license. By contrast, companies and investors have choices as to which early stage technologies to develop and, in taking on this risk and committing to commercialization, require an exclusive license for the full patent term.

3. Did the NIH request the advice of the Attorney General, pursuant to 40 U.S.C. § 559?

As you noted in your letter, NIH has previously explained² that the assertion that 40 U.S.C. § 559 requires NIH to obtain the advice of the Attorney General "regarding whether a patent license would tend to create or maintain a situation inconsistent with antitrust law" is not the long-standing NIH interpretation of the statute.

² Attachment J of your September 13, 2019 letter.

4. Will the licenses tend to substantially lessen competition by creating undue market concentration, in violation of 35 U.S.C. § 209(a)(4)?

You assert in your letter that the proposed license would violate 35 U.S.C. § 209(a)(4)³ because it will tend to substantially lessen competition. This is also not supported by the facts.

CAR technologies are specific for certain surface molecules in a similar manner as antibodies. There are thus multiple types of CAR T-cells that could be developed against a given surface marker. In this case, many CD19 and CD20 antibodies have been produced and have the potential to build competing therapeutics to the ones in this patent family. Scientists are also developing different ways of growing up large numbers of altered T cells in cell cultures and different ways of delivering them back into patients. Changes to the CDR sequences covered by these patents would place an alternative approach outside the scope of the patent. As a result, many different therapeutic permutations can be devised, with the patents subject to this proposed license covering only a limited number.

There are dozens of CAR T-cell companies. NIH itself has granted exclusive and nonexclusive licenses to at least four of them, including Celgene, Cartesian Therapeutics and Novartis. All these companies compete in this field and contribute to the body of scientific knowledge. NIH licenses have encouraged this competition, providing the intellectual property and know-how to make the therapies work and permitting on-going research to develop improved technologies. The companies' success encourages others into the marketplace, with or without technology developed by the NIH.

As you noted in your letter, some of these therapies have been granted orphan drug status by the FDA. That status is reserved by the FDA for therapies or diagnostics with patient populations of 200,000 or less. Because these populations have been historically underserved, Congress created the designation and the exclusivity that goes with it. NIH's grant of exclusive rights for technologies that have the potential to benefit populations with rare diseases is consistent with Congress' intent in this regard, and consistent with the requirements of the Bayh-Dole Act, to provide incentives for companies to develop new therapeutics.

You noted the prices charged by Novartis and Gilead for Yescarta and Kymriah and expressed your concern about prices that may ultimately be charged for therapies resulting from this license. NIH is also concerned about the high prices of drugs and therapies. But NIH has made it clear throughout the years in its public statements⁴ that this problem is one that Congress is in the best position to address. I emphasize that in NIH's judgment for this technology and market,

³ A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention under section 207(a)(2) only if... granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws...

⁴ <https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf>

refusing to grant exclusive rights to these inventions would risk severely limiting the chance that new therapies would be developed for the patients who need them.

5. Was the public's right to evaluate a proposed license undermined by NIH's alleged lack of transparency?

Your assertion that NIH has been less than transparent in its correspondence with KEI regarding exclusive licenses is inaccurate and misleading. From 2016 to 2018, KEI lodged 34 objections to the grant of exclusive licenses out of a total of 51 Federal Register notices of proposed licenses from NIH. In 2019, KEI has lodged objections to nearly all proposed exclusive licenses. NIH has been committed to providing as much information as possible to KEI without breaching its duty to protect confidential information received from its license applicants. NIH cannot, however, provide information that is not available to us, use government resources to create data and reports, or engage in research for KEI.

NIH also declines to address inquiries that have no relevance to the question of whether an exclusive license should be granted. Your letter references communications with NIH's Dr. Lambertson, who you complain did not address several of your questions. These included questions like "in working towards executing this license, has the NIH sought advice from the Attorney General (as is required under 40 USC § 559) to determine if the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law." This of course had been answered previously and has nothing to do with whether NIH should grant an exclusive license. Accordingly, this, and others like it, were properly left unaddressed.

6. Has NIH implemented the objective in the Public Health Service (PHS) Technology Transfer Policy Manual regarding promoting access in developing countries?

That objective, one of at least ten aspirational goals set forth in NIH's policy manual, reads as follows: "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries." Another goal in the policy document recites that "PHS seeks to ensure that commercial partners expeditiously develop the licensed invention." There is, of course, no way to make an invention available in a developing country if there is no commercial partner in the first place who is willing to commit its resources to develop the invention. Achievement of such a goal is even more unlikely if the licensee is hamstrung by restrictions built into its license that limit its marketing activities a dozen years hence. That is the case here, even as NIH continues efforts in appropriate circumstances and to the extent possible to obtain assurances of broad accessibility for developing countries. More generally, NIH leaves doors open for others to commercialize NIH technologies in low income countries by rarely obtaining patents in these jurisdictions.

(2) License in genetically-modified lymphocytes to Intima Biosciences, Inc.

You raised five issues with respect to this proposed license.

1. Did the NIH properly evaluate the necessity of granting an exclusive license in the subject inventions as required by statute.

In your letter regarding the proposed license to Intima Biosciences, Inc. ("Intima") you suggest that, because KEI has been unable to obtain information on the internet regarding the company, the proposed grant is improper.

All patent applications under this proposed license were filed by Intima during a multi-year CRADA with NIH that, unfortunately, failed for scientific reasons to reach its desired endpoints. NIH is aware of the capabilities of the company by virtue of its extensive working relationship in a way that KEI could not be. The patent applications were jointly-invented by Intima, NIH and the University of Minnesota, and their subject matter falls outside of the CRADA research plan. NIH has little scientific interest in developing these inventions further because it believes its resources can be best spent on other candidates.

In your letter you request NIH to reverse its decision to proceed with the license and reopen the license to "competitive bidding."⁵ But NIH did open the license to comments and provided the interested public an opportunity to "bid" on the license when NIH advertised the proposed license grant. That proposed grant is an exclusive license in the government's partial interest in the co-owned patent rights to Intima. NIH received no objections from any potential licensees. Note that, for anyone to bring these inventions to market by obtaining support from investors, they would have to consolidate the rights of all three parties. An exclusive license to NIH's rights in the invention would be *de facto* non-exclusive rights without a consolidation of the other two parties' rights. The best chance that these inventions have for someday reaching the bedside is for the company most interested and invested in them to take them to market. In NIH's considered judgement that company is Intima because it co-owns the patent portfolio and has already invested heavily in its success.

2. Did NIH meet its statutory responsibility to limit the scope of rights to that which is reasonably necessary to induce investment to bring the invention to practical application?

As discussed above, the necessity of granting an exclusive license in this case is indisputable. The scope of the license must also be as broad as needed to attract the necessary investment to get a candidate into a clinical trial. This invention will compete with candidates for the same indication that already appear to be promising.

3. Has the NIH withheld relevant, nonconfidential information about the license from the public, impeding its right to comment on the proposed licenses?

NIH has in fact gone out of its way to respond to each inquiry from KEI, who has objected to virtually every exclusive license proposed by NIH during a several-year campaign. Each of these inquiries comprise approximately twenty pages of questions, many of which have been asked by KEI (and answered by NIH) countless times before or are not relevant to the decision to grant a particular license. Applications that NIH receives from potential licensees typically comprise significant amounts of business confidential information related to their proposed

⁵ Note that NIH does not engage in bidding of license applications based on proposed royalties. Royalties and other terms of a license are not negotiated until the FN period ends and a decision has been made to move forward with a particular license.

commercial plans, including earnings, proposed expenditures and trade secret information. NIH has a duty to safeguard that confidential information. Nevertheless, NIH understands its duty to satisfy the statutory requirements and has made significant efforts to provide non-confidential information available to KEI that is relevant to the license grant.

4. Did the NIH request the antitrust advice of the Attorney General, pursuant to 40 U.S.C. § 559?

As noted above, your conclusion that 40 U.S.C. § 559 is relevant to the grant of exclusive licenses to government-owned inventions is incorrect.

5. Has NIH implemented the objective in the Public Health Service (PHS) Technology Transfer Policy Manual regarding promoting access in developing countries?

That objective, one of at least ten aspirational goals set forth in NIH's policy manual, reads as follows: "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries." Another goal in the policy document recites that "PHS seeks to ensure that commercial partners expeditiously develop the licensed invention." It is, of course, not possible to make an invention available in a developing country if there is no commercial partner willing to commit its resources to develop the invention initially and if there is no patent protection in those countries. Your letter hyperbolically concludes, without evidence or foundation, that "not even making this part of the negotiation is *appalling* and inconsistent with PHS's own stated licensing policies." (Emphasis added) Moreover, KEI can have no way of knowing what has taken place or will take place in NIH negotiations with a potential license because those conversations are strictly confidential. NIH strives to reflect the goals set forth in its licensing policy in the license agreement to the extent possible and appropriate.

Standing

Citing 37 C.F.R. 404.11(a), you assert in your letter that you are entitled to file an appeal of NIH's decision to grant an exclusive license in these cases because KEI employee Clare Love is a lymphoma patient "who could be damaged by the licenses."

37 C.F.R. 404.11 states the following:

In accordance with procedures prescribed by the Federal agency, the following parties may appeal to the agency head or designee any decision or determination concerning the grant, denial, interpretation, modification, or termination of a license: (a) A person whose application for a license has been denied, (b) A licensee whose license has been modified or terminated, in whole or in part; or (c) A person who timely filed a written objection in response to the notice required by § 404.7(a)(1)(i) or § 404.7(b)(1)(i) and who can demonstrate to the satisfaction of the Federal agency that such person may be damaged by the agency action.

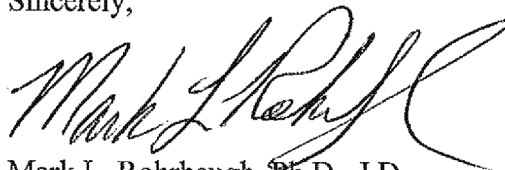
While KEI and associates did apparently file a timely objection to the grant of the exclusive licenses, NIH has determined that neither Ms. Love nor KEI and associates could have, or will be, damaged by the grant of this exclusive license. On the contrary, patients suffering from

cancers presenting these molecular targets might one day be completely cured by the therapies resulting from this early research. As discussed above, NIH determined that, without the grant of an exclusive license in these cases, the likelihood of the development of therapies utilizing these inventions would be significantly diminished. Consequently, if there is any effect at all, it most likely will be that Ms. Love, KEI and its associate will benefit from the grant of the licenses. This is precisely the goal of the NIH patenting and licensing program.

Furthermore, Ms. Love and KEI and associates are too remotely situated to be damaged by this agency action in the sense intended by paragraph (c) of the regulation cited above. That paragraph is generally directed to persons and companies in competition with the intended licensee or participating in the same marketplace. Finally, paragraph (c) clearly leaves the decision as to whether a party has been damaged to the reasonable discretion of the agency, and NIH has determined that you could not be damaged by the grant of this exclusive license.

On behalf of NIH, I thank you again for your comments and your interest in NIH's licensing program.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark L. Rohrbaugh', with a stylized flourish at the end.

Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer
Director, Division of Technology Transfer and
Innovation Policy

From: Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]
Sent: 9/19/2018 3:19:18 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: prospective grant of an exclusive patent license for human therapeutics for type 1 diabetes to a Montreal-based company called Inversago Pharma, Inc., as noticed on August 7, 2018 in the Federal Register (83 FR 38707).
Attachments: NIH to KEI re Inversago T1D 4Sept2018.pdf

From: Shmilovich, Michael (NIH/NHLBI) [E]
Sent: Tuesday, September 04, 2018 11:52
To: 'James Love' <james.love@keionline.org>
Cc: Elizabeth Rowley <elizabeth@t1international.com>; James Elliott <james@t1international.com>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; Manon Ress <manon.ress@keionline.org>; Claire Cassedy <claire.cassedy@keionline.org>; 'elizabeth.rowley@t1international.com' <elizabeth.rowley@t1international.com>
Subject: RE: prospective grant of an exclusive patent license for human therapeutics for type 1 diabetes to a Montreal-based company called Inversago Pharma, Inc., as noticed on August 7, 2018 in the Federal Register (83 FR 38707).

Mr. Love et al. - Thank you for your comments which have considered carefully. NIH's response is enclosed.

Warm Regards,

Michael A. Shmilovich, Esq., CLP



National Heart, Lung,
and Blood Institute

Office of Technology Transfer and Development
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Bethesda, MD 20892-2479
o. 301.435.5019
shmilovm@mail.nih.gov

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"Always be yourself...unless you can be a pirate... then; obviously, be a pirate"

From: James Love <james.love@keionline.org>
Sent: Monday, August 20, 2018 10:39
To: Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Cc: Elizabeth Rowley <elizabeth@t1international.com>; James Elliott <james@t1international.com>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; Manon Ress <manon.ress@keionline.org>; Claire Cassedy <claire.cassedy@keionline.org>
Subject: prospective grant of an exclusive patent license for human therapeutics for type 1 diabetes to a Montreal-based company called Inversago Pharma, Inc., as noticed on August 7, 2018 in the Federal Register (83 FR 38707).

Dear Michael A. Shmilovich, Esq., CLP

REL0000024855

Attached are comments by Knowledge Ecology International (KEI) and T1International on the prospective grant of an exclusive patent license for human therapeutics for type 1 diabetes to a Montreal-based company called Inversago Pharma, Inc., as noticed on August 7, 2018 in the Federal Register (83 FR 38707).

J
ames Love

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

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National Heart, Lung,
and Blood Institute

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31 Center Drive Room 4A29, MSC2479
Bethesda, MD 20892-2479
Michael Shmilovich, Esq., CLP
shmilovm@mail.nih.gov

September 4, 2018

James Packard Love
Elizabeth Rowley

IN RE: 83 Fed. Reg. 152 (August 7, 2018), "Prospective Grant of Exclusive Patent License: type I diabetes and its comorbidities diabetic nephropathy, chronic kidney disease, diabetic retinopathy, and peripheral and autonomic neuropathy" to Inversago Pharma, Inc. (Inversago).

Dear Ms. Rowley and Mr. Love:

Thank you for providing us with your comments regarding the aforementioned Federal Register notice.

Prior to posting notices for a proposed grant of an exclusive license, the NIH determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company is qualified both technically and financially to be granted an exclusive license to the Government's intellectual property in the fields of use as specified and especially in this case since Inversago has already been granted an exclusive license to the same patent estate for a different field of use. The notice period provides an opportunity for public comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license and have considered your comments.

With regards to this license in particular, after extensive discussions with Inversago prior to their application for license and in view of their successful efforts to raise money for the company, we are satisfied that the application they provided, which includes a comprehensive commercial development plan, demonstrates that the company is both scientifically and financially capable of developing a type I diabetes therapeutic from the cannabinoid receptor 1 reverse agonists covered by the Government's patent rights. Moreover, the pre-clinical and preliminary clinical testing Inversago would be required to undertake in furthering development in any field would also be required for a type I therapeutic since the mechanism of action is essentially the same. Because the FDA considers type I and type II diabetes to be different disorders we feel that it is appropriate to issue separate licenses predicated on separate development plans.

Lastly, we do not consider a grant of this specific patent estate in the type I diabetes field to Inversago to give rise to a monopoly. There are several therapeutics for type I diabetes available both domestically and worldwide: Surinabant (Sanofi), Ibipinabant (Solvay Therapeutics), and Brizantin (mAb), to name a few. Further, prior to discussing a potential application for license with Inversago, NIH offered another licensee of these rights to apply for a license to the this field and they declined. Given the new industry wide interest in exploiting the endocannabinoid system as a target for therapy that the CNR1 and CNR2 receptors, pertinent in particular to the instant patent estate, are expressed in a variety of tissue types and that there are many potential therapeutic fields available besides diabetes. With regards to Type I Diabetes, NIH has other patent positions claiming therapeutics and therapeutic methods against type I diabetes available and one need only do a search using the term "type I diabetes" on our available technologies website <https://www.ott.nih.gov/opportunities> to see that there are not less than 16 patent estates that address this public health concern.

If your organization requests more documentation, such requests should be filed under the Freedom of Information Act. The webpage for the NIH FOIA Office provides more information on filing requests <http://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests>.

Sincerely,

b6

Michael A. Shmilovich, Esq., CLP

REL0000024855.0001

From: Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]
Sent: 9/19/2018 3:19:43 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: In Re: 83 FR 35667 -- Prospective Grant of Exclusive Patent License: Radiotherapy for Metastatic Castration-Resistant Prostate Cancer to Sinotau
Attachments: NIH to KEI re Sinotau 6Sept2018.pdf

From: Shmilovich, Michael (NIH/NHLBI) [E]
Sent: Thursday, September 06, 2018 11:33
To: 'James Love' <james.love@keionline.org>; 'Luis Gil Abinader' <luis.gil.abinader@keionline.org>; 'Manon Ress' <MANON.RESS@cancerunion.org>
Subject: In Re: 83 FR 35667 -- Prospective Grant of Exclusive Patent License: Radiotherapy for Metastatic Castration-Resistant Prostate Cancer to Sinotau

Dear Mr. Love, Mr. Abinader and Dr. Ress,

Thank you for your comments to the above referenced FR notice, we have considered them and respectfully enclose our response.

Regards,

Michael A. Shmilovich, Esq., CLP

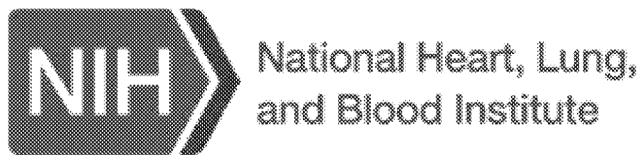


National Heart, Lung,
and Blood Institute

Office of Technology Transfer and Development
31 Center Drive Room 4A29, MSC2479
Bethesda, MD 20892-2479
o. 301.435.5019
shmilovm@nih.gov

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REL0000024856



Office of Technology Transfer and Development
31 Center Drive Room 4A29, MSC2479
Bethesda, MD 20892-2479
Michael Shmilovich, Esq., CLP
shmilovm@mail.nih.gov

September 6, 2018

James Love
Luis Gil Abinader
Dr. Manon Anne Ress

IN RE: Prospective Grant of Exclusive Patent License: Radiotherapy for Metastatic
Castration-Resistant Prostate Cancer (83 FR 35667) to Sinotau Pharmaceutical Group (Sinotau).

Dear Mrs. Love, Abinader and Dr. Ress:

Thank you for providing us with your comments regarding the aforementioned Federal Register notice.

Prior to posting notices of a proposed grant of exclusive commercialization licenses, the NIH determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company applying is qualified both technically and financially to be granted an exclusive license to the Government's intellectual property in the field specified. The notice period provides an opportunity for public comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license and have considered your comments.

With regards to this license in particular, after extensive discussions with Sinotau and after reviewing their application, which included a comprehensive commercial development plan, we determined that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied. Sinotau possesses the requisite scientific and financial capability for developing a radiotherapeutic that targets metastatic castration-resistant prostate cancer and that the scope of the license proposed is reasonable and necessary given the difficulty of developing a therapeutic of that kind and on balance with the Government's interest in promoting the public health and public access to drugs. The patent estate intended for licensure is early stage and currently in the provisional patent application stage (U.S. provisional patent application 62/633,648 filed February 22, 2018). If we opt to continue pursuing rights in this invention by filing an international patent application under the Patent Cooperation Treaty, we expect the application as filed to be published by the end of August 2019 pursuant to the 18-month publication rule (PCT Article 21).

Sinotau is not the only company that expressed interest in this patent estate and we provided copies of the provisional patent application and corresponding publications (see Appendix A) to companies under confidentiality nondisclosure agreements. Thereafter, only Sinotau applied for a license.

We have read through and considered the terms and suggestions you proffered in points 1. through 4 of your letter. If your organization requests more documentation, such requests should be filed under the Freedom of Information Act. The webpage for the NIH FOIA Office provides more information on filing requests <http://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests>.

Sincerely,

b6

Michael A. Shmilovich, Esq., CLP

REL0000024856.0001

APPENDIX A – Publication citations

Single Low-Dose Injection of Evans Blue Modified PSMA-617 Radioligand Therapy Eliminates Prostate-Specific Membrane Antigen Positive Tumors.

Wang Z, Tian R, Niu G, Ma Y, Lang L, Szajek LP, Kiesewetter DO, Jacobson O, Chen X.

Bioconjug Chem. 2018 Aug 22. doi: 10.1021/acs.bioconjchem.8b00556. [Epub ahead of print]

PMID: 30105912

First-in-human study of ^{177}Lu -EB-PSMA-617 in patients with metastatic castration-resistant prostate cancer.

Zang J, Fan X, Wang H, Liu Q, Wang J, Li H, Li F, Jacobson O, Niu G, Zhu Z, Chen X.

Eur J Nucl Med Mol Imaging. 2018 Aug 8. doi: 10.1007/s00259-018-4096-y. [Epub ahead of print]

PMID: 30090965

Radioligand Therapy of Prostate Cancer with a Long-Lasting Prostate-Specific Membrane Antigen Targeting Agent ^{90}Y -DOTA-EB-MCG.

Wang Z, Jacobson O, Tian R, Mease RC, Kiesewetter DO, Niu G, Pomper MG, Chen X.

Bioconjug Chem. 2018 Jul 18;29(7):2309-2315. doi: 10.1021/acs.bioconjchem.8b00292. Epub 2018 Jun 15.

PMID: 29865797

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 10/8/2019 4:06:37 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Question, Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer 84 FR 52890

From: Burke, Andy (NIH/NCI) [E]
Sent: Tuesday, October 8, 2019 12:06 PM
To: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Subject: RE: Question, Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer 84 FR 52890

Dear Ms. Ardizzone,

Thank you for your email. Technology reference E-029-2019 is listed as available for license on the NCI Technology Transfer website under the section "Available Technologies." Please see, for example, the marketing abstract titled "T Cell Receptors Targeting KRAS Mutants for Cancer Immunotherapy/Adoptive Cell Therapy."

Regards,

Andy

Andrew R. Burke, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute
9609 Medical Center Drive, Rm 1E550
Rockville, MD 20850

Direct: (240) 276-5484
Email: andy.burke@nih.gov

NOTE: This email or its attachments may contain confidential information. It is intended only for the addressee(s) identified above. If you are not the addressee(s), or an employee or agent of the addressee(s), please note that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this email in error, please destroy the document and notify the sender.

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Tuesday, October 8, 2019 11:26 AM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Subject: Question, Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer 84 FR 52890

Dear Dr. Burke:

Public comments on the NIH's Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer, noticed at 84 FR 52890, are due October 18.

The Notice pertains to two inventions: E-029-2019 ("Invention A") and E-135-2019 ("Invention B").

REL0000024857

According to the Technology Transfer Office's website, the first stage of the licensing process for an HHS invention is that a potential licensee can "Use the Find Technologies section at the right of the webpage screen to search for and view abstracts describing HHS technologies available for licensing." <https://www.ott.nih.gov/licensing/licensing-process>

The Find Technologies search engine has a field for NIH OTT Ref. No. When I entered the Ref. No. for Invention A in the search engine, no results were returned. Why is that? Did NIH publish a licensing opportunity notice for Invention A?

Thank you,

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From: Freel, Rose (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8AE9AAB7E3249E881BB573E9A189036-FREELRM]
Sent: 7/23/2018 8:28:09 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer to Atara Biotherapeutics Inc.
Attachments: NCIResponsetoKEI_7.23.2018_83FR30448.pdf

Hi Mark,

See attached and below for the final letter I sent KEI.

Thanks!
Rose

--

Rose Santangelo Freel, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute
P 301-624-1257 | rose.freel@nih.gov

From: Freel, Rose (NIH/NCI) [E]
Sent: Monday, July 23, 2018 4:28 PM
To: 'James Love' <james.love@keionline.org>
Subject: RE: Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer to Atara Biotherapeutics Inc.

Dear Mr. Love,

Please see the attached response to your comments.

Best Regards,
Rose

--

Rose Santangelo Freel, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute
P 301-624-1257 | rose.freel@nih.gov

From: James Love <james.love@keionline.org>
Sent: Friday, July 13, 2018 4:45 PM
To: Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>
Cc: Tim Reed <Tim@haiweb.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; Merith Basey <merith@essentialmedicine.org>; Alex Lawson <alawson@socialsecurityworks.org>; Fran Quigley <fquigley@gmail.com>; Baker, Brook <b.baker@northeastern.edu>; Meg Jones-Monteiro <mjonesmonteiro@iccr.org>; Manon Ress <MANON.RESS@cancerunion.org>; Claire Cassedy <claire.cassedy@keionline.org>; Thiru Balasubramaniam <thiru@keionline.org>
Subject: Re: Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer to Atara Biotherapeutics Inc.

REL0000024858

Dear Dr. Freel,

I'm attaching a corrected copy of the comments. The difference was just the spelling of CFR, which had been transposed in the earlier version.

Jamie

On Fri, Jul 13, 2018 at 4:09 PM, James Love <james.love@keionline.org> wrote:

Dr. Freel,

Attached are comments on the Atara license from:

Health Action International (HAI)
Health GAP
Interfaith Center on Corporate Responsibility (ICCR)
Knowledge Ecology International (KEI)
People of Faith for Access to Medicines (PFAM)
Social Security Works (SSW)
Union for Affordable Cancer Treatment (UACT)
Universities Allied for Essential Medicines (UAEM)

--

James Love, Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, twitter.com/jamie_love

--

James Love, Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, twitter.com/jamie_love



National Institutes of Health
National Cancer Institute
Technology Transfer Center
8490 Progress Drive
Riverside 5 building, Suite 400
Frederick, MD 21701
Phone (301) 624-8775
FAX (301) 631-3033

via email only

July 23, 2018

James Love
Knowledge Ecology International (KEI)
1621 Connecticut Avenue, Suite 500,
Washington DC 20009

RE: Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin
Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer (83 FR 30448)

Dear Mr. Love,

Thank you for providing us with your comments in response to the Federal Register Notice of the proposed license to Atara Biotherapeutics (Atara) by the National Cancer Institute (NCI). We have reviewed and considered all of your comments and the specific recommendations you provided regarding terms to be included in the license related to the pricing of products, the term of exclusivity, the exclusivity and access in developing countries, and the transparency of the licensee's development through annual reporting.

With respect to your comments regarding the pricing of products in the US and developing countries, the NIH has not included terms related to pricing in its licenses for many years. The reasons for this are well established and are publicly available.

With respect to your comments regarding transparency of information regarding clinical trial outlays and research and development costs by the licensee, these are business confidential information that, under the licensing statute, cannot be disclosed.

Sincerely,

Rose M. Freel, Ph.D.
Senior Technology Transfer Manager
NCI Technology Transfer Center

From: Pollard, Ricquita (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DC946982E43F43CB925773EA52C40AFA-POLLARDRD]
Sent: 9/18/2018 9:23:45 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Chatterjee, Sabarni (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4520fc058d6457aac24b57685235b12-chatterjees]
Subject: RE: response to KEI
Attachments: RE_ Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665.pdf; Response to KEI_comments on A-311-2018_092018_RP_MLR--OGCBerkleyComments.docx

Hi Mark,

Yes, you remembered perfectly. I have attached the response sent to KEI and UACT on September 7th as well as a draft copy with additional edits from Dale.

I hope this helps.

-Ricquita

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, September 18, 2018 4:33 PM
To: Pollard, Ricquita (NIH/NCI) [E] <ricquita.pollard@nih.gov>
Cc: Chatterjee, Sabarni (NIH/NCI) [E] <sabarni.chatterjee@nih.gov>
Subject: response to KEI

Ricquita:

I recall you were working on a response to KEI recently. Did I remember correctly? If so, could you send me the final response you sent them or when you send it.

THanks

Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer
Director, Division of Technology Transfer and Innovation Policy
Office of Science Policy
Office of the Director
National Institutes of Health

REL0000024859

From: Pollard, Ricquita (NIH/NCI) [E]
To: "James Love"
Subject: RE: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665
Date: Friday, September 07, 2018 2:15:00 PM
Attachments: Response to KEI UACT comments re Midissia.pdf

Dear James,

Please see the attached letter in response to your comments.

Thanks,
Ricquita

Ricquita D. Pollard, Ph.D.

Technology Transfer Manager
Technology Transfer Center
National Cancer Institute
9609 Medical Center Drive, Rm 1-E530
Bethesda, MD 20892-9702 (for business mail)
Rockville, MD 20850-9702 (for courier service/visitors)
Phone (Main Office): (240) 276-5530
Direct Phone: (240) 276-5490
Fax: (240) 276-5503
pollardrd@mail.nih.gov

<https://ttc.nci.nih.gov/index.php>

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From: James Love <james.love@keionline.org>
Sent: Monday, August 13, 2018 11:48 PM
To: Pollard, Ricquita (NIH/NCI) [E] <ricquita.pollard@nih.gov>
Subject: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665

August 13, 2018

Ricquita Pollard, Technology Transfer Manager,
NCI Technology Transfer Center,
Via Email: pollardrd@mail.nih.gov.

Re: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665

Dear Ricquita Pollard:

The following are comments from Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT), on the proposed exclusive license for patents noticed in the Federal Register for a license to Midissia Therapeutics ("Midissia") located in San Francisco, California.

1. No discrimination against US residents in pricing

We ask that the NIH include language in the proposed exclusive license to ensure that the prices in the U.S. for any drug, vaccine, medical device or other health technology using the inventions are not higher than the median price charged in the seven countries with the largest gross domestic product (GDP), that also have a per capita income of at least 50 percent of the United States, as measured by the World Bank Atlas Method.

We consider this a modest request to protect U.S. residents, who paid for the R&D that created the licensed inventions.

2. Reduce term of exclusivity when revenues are large

In addition to an external reference pricing test, we propose that the exclusivity of the license in the U.S. should be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks.

Given the modest cost of acquiring an NIH patented invention, the amount of money the developer needs in sales to justify additional investments in R&D is reduced, as compared to cases where a company develops or acquires the technology from non government sources.

This request is consistent with the statutory requirements of 35 USC 209, which requires that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application."

One possible implementation of revenue benchmarks is as follows: exclusivity will be reduced by one year for every \$500 million in revenue equivalents, earned after the first \$1 billion, where revenue equivalent is defined as global cumulative sales plus market entry rewards as well as government grants or tax credits, for the product or products using the invention. However, the NIH could choose different benchmarks, so long as the limits on exclusivity address the requirements of 35 USC 209, that the incentive is "not greater than reasonably necessary."

3. Developing countries

We are concerned that several NIH funded inventions are not accessible in developing countries, due to prices that are high and not affordable in markets where

per capita incomes are significantly lower than the United States. For this reason, we ask the NIH to limit the exclusivity in the license to countries that have per capita incomes that are at least 30 percent of the United States.

We also ask the NIH to reach out to the Medicines Patent Pool (MPP), in order to enter into an agreement that gives the MPP an option to negotiate non-exclusive open licenses for the inventions in developing countries.

4. Transparency

The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 USC 209, that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application." Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to market.

Sincerely,

James Love
Knowledge Ecology International

Manon Anne Ress
Union for Affordable Cancer Treatment

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,

twitter.com/jamie_love

September 7, 2018

James Love
Scientific and Technical Advisor
Knowledge Ecology International

Manon Anne Ress
Union for Affordable Cancer Treatment

IN RE: Your Letter Dated August 13, 2018 in response to 83 FR 35663, Published July 27, 2018
"Prospective Grant of Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy"

Dear James Love and Manon Ress:

Thank you for providing us with your comments regarding the notice of the proposed license the National Cancer Institute (NCI) intends to grant to Midissia Therapeutics. Prior to posting a notice for a proposed grant of an exclusive license, the NIH determines that the statutory and regulatory requirements set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company is qualified both technically and financially to be granted an exclusive license to the Government's intellectual property in the fields of use as specified. Furthermore, the company has demonstrated capabilities to productively advance the technology of interest to a state which is safe and a superior alternative to the existing standard of care. The notice period provides an opportunity for public comment and possible objection to the proposed license.

We consider all comments prior to negotiating the proposed license and have considered your comments. Please see responses to your comments below:

- 1) Regarding your proposal to include language in the proposed exclusive license to ensure that the prices in the U.S. for any drug, vaccine, medical device or other health technology using the inventions are not higher than the median price charged in the seven countries with the largest gross domestic product (GDP), that also have a per capita income of at least 50 percent of the United States, as measured by the World Bank Atlas Method, please note that the NIH has not included pricing provisions in its licenses for many years for reasons that are readily and publicly available.
- 2) With respect to your comments on reducing term of exclusivity when revenues are large, NIH has determined that such terms would deter companies from licensing and developing products in contradiction of the goals stated in the applicable regulations and statutes.
- 3) Regarding your comment on reducing exclusivity in the license to countries that have per capita incomes that are at least 30 percent of the United States, it should be noted that intellectual property rights for this technology will apply to countries, as appropriate. The technology is currently in the National Stage of patent prosecution, and it is highly unlikely that NCI will seek patent protection in the developing world. In countries where the NCI has no valid, issued patent(s), the technology may be exploited without risk of infringement.
- 4) In response to your comment on transparency, NCI's licenses do require routine reporting on product development, sales and royalty payments. However, these reports are proprietary to the

company and cannot be released by NCI without the company's permission. Please refer to 37 C.F.R. 404.14 for additional details.

Accordingly, we believe that the grant of an exclusive license to Midissia in a field of use substantially as advertised in the Federal Register furthers the spirit and letter of the laws and regulations that authorize the grant of the license.

Please let me know if you have any questions.

Sincerely,

b6

Ricquita Pollard, Ph.D.
Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH

b5

b5

Sincerely,

Ricquita Pollard, Ph.D.
Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH

From: Reichman, Uri (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E7AFFA5D8E64E8C9783C67B500D8DB8-REICHMAU]
Sent: 10/8/2019 5:11:06 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Shmilovich, Michael (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dfe19bfd1d443ceb700b9f22d159a90-shmilovm]; Devany, John (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7616e9f906f43adac8d838de12a7bf1-devanyjr]
Subject: RE: Additional Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

OK Thanks! As to the date of the notice they should know it themselves, the date is stated in the notice!

Best!

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Tuesday, October 8, 2019 11:25 AM
To: Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>
Cc: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>; Devany, John (NIH/NHLBI) [E] <john.devany@nih.gov>
Subject: RE: Additional Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

We are not going to answer the question (just ignore it, not comment on it) but you can tell them when notice was first published.

From: Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>
Sent: Tuesday, October 8, 2019 11:22 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>; Devany, John (NIH/NHLBI) [E] <john.devany@nih.gov>
Subject: FW: Additional Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Hi Mark,

Here is another one from KEI. Can you respond to them?

Thanks,

Uri

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Monday, October 7, 2019 5:33 PM
To: Reichman, Uri (NIH/NHLBI) [E] <uri.reichman@nih.gov>
Subject: Additional Questions, Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

Dear Dr. Reichman:

REL0000024860

As you know, Section 209(e) of the Bayh Dole Act guarantees the public's right to comment on a proposed exclusive patent license.

In relation to the licenses noticed at 84 FR 51171, you have:

- stated that the term of the licenses are to be decided;
- stated that the NIH's reasons for granting exclusivity are confidential;
- stated that the field of use listed is as broad as possible, because it is yet to be decided;
- stated that the NIH cannot tell us what other entities have applied for the license, because that information is confidential; and
- stated that how the NIH ensures that the licenses comply with the limitations governing scope is confidential.

If the terms of the license and how the NIH complies with the Bayh Dole Act are either undetermined or confidential or both, then what is the public's role in the notice and comment process guaranteed under Section 209?

Also, can you please state when the licensing opportunity notice E-241-2010 was first published?

Thank you,

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 9/20/2019 3:14:40 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

Hi Mark,

Here's a copy of my recent response to a records request embedded in KEI's recent objection commentary. I am in the process of drafting a response to the objections themselves.

Thank you,

Andy

From: Burke, Andy (NIH/NCI) [E]
Sent: Friday, September 20, 2019 11:12 AM
To: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Subject: RE: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

Dear Ms. Ardizzone,

On page nine (9) of your submitted comments you make the following request:

"...that the NIH provide us, from the license application, the items described at 37 C.F.R. 404.8(a)(1)-(7),(9)-(11), and the public provisions of any related CRADA..."

The mechanism to request such information is under 5 U.S.C. 552 ("Freedom of Information Act"). A link to the NCI FOIA webpage is provided below for your reference.

<https://www.cancer.gov/policies/foia>

Regards,

Andy

Andrew R. Burke, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute
9609 Medical Center Drive, Rm 1E550
Rockville, MD 20850

Direct: (240) 276-5484
Email: andy.burke@nih.gov

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REL0000024861

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Friday, September 13, 2019 5:23 PM

To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Cc: James Love <james.love@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>;
manon.ress@cancerunion.org; Peter Maybarduk <pmaybarduk@citizen.org>; Steve Knievel <sknievel@citizen.org>;
ruth.lopert@gmail.com; lovesplumbing@comcast.net; Alex Lawson <alawson@socialsecurityworks.org>

Subject: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

Dear Dr. Burke:

Attached, please find the comments of Knowledge Ecology International (KEI), Union for Affordable Cancer Treatment (UACT), Public Citizen (PC), Social Security Works (SSW), LWC Health, Ruth Lopert, Manon Ress, and Terry Love regarding "Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy," 84 FR 45503, and the associated attachments.

Thank you in advance for processing and considering these comments.

Sincerely,

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From: Knabb, Jim (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=535517D229E04963A2B928742CB80DA0-KNABBJR]
Sent: 9/5/2019 6:34:27 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: response to KEI re: E-106-2015 and E-017-2017
Attachments: response to KEI JK 9-5 MLR-JK V2.docx

Thanks a ton Mark, I accepted the majority of your changes and made modifications in response to your comments. If this looks OK I'll send it on its way.

Best,
Jim

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Thursday, September 5, 2019 2:11 PM
To: Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>
Subject: RE: response to KEI re: E-106-2015 and E-017-2017

Thanks Jim. See my suggestions and comments in the attached.

From: Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>
Sent: Thursday, September 5, 2019 1:58 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: response to KEI re: E-106-2015 and E-017-2017

Hi Mark,

Could you please review my proposed responses to KEI in response to their comments that I've attached as a pdf?

Thanks,
Jim

September 5, 2019

Kathryn Ardizzone, Esq.

Re: Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22
Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies Federal Register / Vol. 84,
No. 161 / Tuesday, August 20, 2019

Dear Kathryn,

b5

Sincerely,

Jim Knabb, Ph.D.

From: Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]
Sent: 7/23/2018 12:23:45 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Draft KEI Response
Attachments: A-301-2018_Response to KEI_5 July 2018.docx; A-301-2018_Response to KEI.pdf

Good morning Mark,

Here is the letter that I sent. Since no one provided additional comments, it is merely Dale's version with his changes accepted. Let me know if you have additional questions.

Dave

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
Phone (direct): (240) 276-6467
Fax: 240-276-5504

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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, July 19, 2018 4:57 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: RE: Draft KEI Response

Dave:

Did you send me the final?

Thanks

From: Lambertson, David (NIH/NCI) [E]
Sent: Thursday, July 05, 2018 7:05 AM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: RE: Draft KEI Response

Thanks Dale.

REL0000024863

Please let me know if anyone else has any further comments on Dale's version by this afternoon. Otherwise I will send this version to KEI.

Cheers,
Dave

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
<http://ttc.nci.nih.gov/>

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Fax: 240-276-5504

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From: Berkley, Dale (NIH/OD) [E]
Sent: Tuesday, July 03, 2018 11:27 AM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: RE: Draft KEI Response

I have a number of edits and comments in the attached. As I note there,

b5

b5

Best, Dale

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

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From: Lambertson, David (NIH/NCI) [E]
Sent: Monday, July 02, 2018 4:04 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: Draft KEI Response

Good afternoon Mark and Dale,

REL0000024863

I attach a draft response to KEI, who has objected to a recent Notice of Intent to Grant an exclusive license, for your review and consideration. Please let me know if you think the response is acceptable or if you would suggest changes before the response is sent. If you need anything else, let me know.

Thanks,
Dave

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
<http://ttc.nci.nih.gov/>

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10 July 2018

VIA E-MAIL ONLY

James Love
Knowledge Ecology International
1621 Connecticut Ave. NW, Suite 500
Washington, DC 20009

IN RE: Prospective Grant of an Exclusive License (NIH License Application A-301-2018) to BEORO
Therapeutics, GmbH, published on 7 June 2018 in *Federal Register* Vol. 83, No. 110, page 26847

Dear Mr. Love:

Thank you for providing us with your comments regarding the notice of the proposed license to BEORO
Therapeutics, GmbH (BEORO), by the National Cancer Institute (NCI) on behalf of KEI and six other groups.

Prior to posting a notice for a proposed grant of an exclusive license, the NCI determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company is qualified to be granted an exclusive license to the Government's intellectual property in the fields of use as specified. The notice period provides an opportunity for public comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license.

We have considered your comments and address them in the following:

- 1) With respect to your comments that the license not be granted unless (a) the "NIH has determined that an exclusive license is 'a reasonable and necessary incentive' to induce investments for the development and practical application of the invention," and (b) the NIH limits the scope of rights for the exclusivity only to those rights reasonably necessary, those determinations were made prior to the advertisement of the proposed license.
- 2) With respect to your recommendations regarding pricing of products made by the licensee, NIH has not included pricing provisions in its licenses for many years, for reasons that have been extensively discussed in the literature, which is readily and publicly available.
- 3) With respect to your comments regarding the availability of the invention for research purposes, the NIH does, in fact, retain the right to grant research-only licenses to interested parties.
- 4) You suggested in your letter that we require BEORO to publicly disclose its research and development costs, the amount of money spent each year on clinical trials, relevant tax credits, grants and other subsidies received from governments or charities, the prices and revenue derived from its products, the number of units sold, its research and development outlays, and relevant patents and regulatory approvals obtained in each country. That suggestion is entirely impractical. To the extent that this information is not already publicly available, it is generally confidential business information that could damage the business and competitive position of our licensee if publicly disclosed. We require our license applicants to provide us with sufficient information to evaluate the viability of their commercial plans and we carefully maintain the confidentiality of that information as required by 37 C.F.R. 404.14.



Again, thank you for your comments regarding this proposed license. We don't see any issues that would preclude the grant of the proposed exclusive license, and we will proceed with its negotiation. If I can be of any further assistance, please let me know.

Sincerely,
David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute, TTC
david.lambertson@nih.gov



10 July 2018

VIA E-MAIL ONLY

James Love
Knowledge Ecology International
1621 Connecticut Ave. NW, Suite 500
Washington, DC 20009

IN RE: Prospective Grant of an Exclusive License (NIH License Application A-301-2018) to BEORO
Therapeutics, GmbH, published on 7 June 2018 in *Federal Register* Vol. 83, No. 110, page 26847

Dear Mr. Love:

Thank you for providing us with your comments regarding the notice of the proposed license to BEORO
Therapeutics, GmbH (BEORO), by the National Cancer Institute (NCI) on behalf of KEI and six other groups.

Prior to posting a notice for a proposed grant of an exclusive license, the NCI determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company is qualified to be granted an exclusive license to the Government's intellectual property in the fields of use as specified. The notice period provides an opportunity for public comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license.

We have considered your comments and address them in the following:

- 1) With respect to your comments that the license not be granted unless (a) the "NIH has determined that an exclusive license is 'a reasonable and necessary incentive' to induce investments for the development and practical application of the invention," and (b) the NIH limits the scope of rights for the exclusivity only to those rights reasonably necessary, those determinations were made prior to the advertisement of the proposed license.
- 2) With respect to your recommendations regarding pricing of products made by the licensee, NIH has not included pricing provisions in its licenses for many years, for reasons that have been extensively discussed in the literature, which is readily and publicly available.
- 3) With respect to your comments regarding the availability of the invention for research purposes, the NIH does, in fact, retain the right to grant research-only licenses to interested parties.
- 4) You suggested in your letter that we require BEORO to publicly disclose its research and development costs, the amount of money spent each year on clinical trials, relevant tax credits, grants and other subsidies received from governments or charities, the prices and revenue derived from its products, the number of units sold, its research and development outlays, and relevant patents and regulatory approvals obtained in each country. That suggestion is entirely impractical. To the extent that this information is not already publicly available, it is generally confidential business information that could damage the business and competitive position of our licensee if publicly disclosed. We require our license applicants to provide us with sufficient information to evaluate the viability of their commercial plans and we carefully maintain the confidentiality of that information as required by 37 C.F.R. 404.14.



Again, thank you for your comments regarding this proposed license. We don't see any issues that would preclude the grant of the proposed exclusive license, and we will proceed with its negotiation. If I can be of any further assistance, please let me know.

Sincerely,
David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute, TTC
david.lambertson@nih.gov

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 9/27/2019 3:10:41 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

My submitted response

From: Burke, Andy (NIH/NCI) [E]
Sent: Friday, September 27, 2019 11:07 AM
To: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Subject: RE: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

Dear Ms. Ardizzone,

I referred you to my previous response because that answer remains correct. As you know from past correspondence with my office, the term of a license is a product of negotiation and is therefore not fixed until the agreement is executed. As you are also aware, the terms of an executed license are business confidential information.

Regards,

Andy

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Friday, September 27, 2019 9:39 AM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: James Love <james.love@keionline.org>
Subject: Re: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

Dear Dr. Burke,

Thank you for your email. I have referred to your September 10 email where the question is addressed. It states:

Question: Please confirm or deny whether the license will "extend to the expiration of the last to expire of the Licensed Patent Rights" as provided in the NIH Model Exclusive Patent License Agreement.

Answer: This has not yet been determined.

Since September 10, 17 days have passed, and the NCI has rejected KEI's comments and determined that the license is appropriate. As you are aware, under Section 209 of the Bayh Dole Act, this requires that NCI has determined that the scope (including term) of the license is not greater than reasonably necessary. So, presumably something should have changed since your September 10 email.

I will pose the question to you again: Has the NCI established the duration of the prospective license to Intima Bioscience? Answer: No

A "yes" or "no" answer would be responsive, and it would be appreciated.

REL0000024864

If your answer is "yes," what is the term?

If your answer is "no," when do you anticipate making such a determination? Answer: Currently unknown, since the timeline of negotiation is determined as much by the responsiveness of the counterparty as it is by the NCI.

Thank you in advance for your assistance with these questions.

Kathryn Ardizzone

On Fri, Sep 27, 2019 at 9:24 AM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Dear Ms. Ardizzone,

Please refer to my email of September 10 where this questions is addressed.

Regards,

Andy

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Thursday, September 26, 2019 4:42 PM

To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Subject: Re: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

Dear Dr. Burke,

Thank you for forwarding the NCI's final determination regarding KEI's comments on the license to Intima Bioscience.

Is the period of exclusivity for the subject license life of patent? Please let us know, as this pertains to a possible basis on which we may appeal the determination.

Sincerely,
Kathryn Ardizzone

On Thu, Sep 26, 2019 at 4:31 PM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Dear Ms. Ardizzone,

Please find attached a response to your comments regarding the referenced Federal Register notice.

Sincerely,

Andy

Andrew R. Burke, Ph.D.

Senior Technology Transfer Manager

National Cancer Institute

9609 Medical Center Drive, Rm 1E550

Rockville, MD 20850

Direct: (240) 276-5484

Email: andy.burke@nih.gov

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From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Friday, September 13, 2019 5:23 PM

To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Cc: James Love <james.love@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>;
manon.ress@cancerunion.org; Peter Maybarduk <pmaybarduk@citizen.org>; Steve Knievel <sknievel@citizen.org>;
ruth.lopert@gmail.com; lovesplumbing@comcast.net; Alex Lawson <alawson@socialsecurityworks.org>

Subject: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

REL0000024864

Dear Dr. Burke:

Attached, please find the comments of Knowledge Ecology International (KEI), Union for Affordable Cancer Treatment (UACT), Public Citizen (PC), Social Security Works (SSW), LWC Health, Ruth Lopert, Manon Ress, and Terry Love regarding "Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy," 84 FR 45503, and the associated attachments.

Thank you in advance for processing and considering these comments.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

--

Kathryn Ardizzone, Esq.

Counsel

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kathryn.ardizzone@keionline.org

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--

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Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 9/11/2019 8:45:15 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

From: Burke, Andy (NIH/NCI) [E]
Sent: Wednesday, September 11, 2019 4:45 PM
To: kathryn ardizzone <kathrynardizzonekei@gmail.com>
Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>
Subject: RE: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Ms. Ardizzone,

Answers to your questions are provided below.

Regards,

Andy

From: kathryn ardizzone <kathrynardizzonekei@gmail.com>
Sent: Wednesday, September 11, 2019 2:29 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>
Subject: Re: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Dr. Burke:

Thank you for your response.

Given the lack of publicly-available data about the company (no website, no registration in NY, no officers or contact information for those officers listed in Delaware corporate records), how do you propose that KEI request this information directly from the company? Answer: The company's mailing address is publicly-available, as is a phone number. Please see, for example, <https://start.cortera.com/company/research/l6o5lxm2r/intima-bioscience-inc/>.

Also, please clarify why you are unable to release this information. Answer: Please see 37 CFR 404.14

Finally, please explain how the public can be ensured that Intima Bioscience, Inc. is an appropriate licensee, who can bring the invention to market, without even knowing who its principals are, and without the ability to contact them directly for that information.

Thank you,
Kathryn Ardizzone

On Wed, Sep 11, 2019 at 1:40 PM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

REL0000024866

Dear Ms. Ardizzone,

I am unable to release this information. You may, however, request it directly from the company.

Regards,

Andy

From: kathryn ardizzone <kathrynardizzonekei@gmail.com>

Sent: Wednesday, September 11, 2019 12:59 PM

To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>

Subject: Re: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Thank you, Andy.

Can you please answer our question about Intima Bioscience's principals/list the members of its board of directors? We believe that is not too much to ask, considering that this information is not publicly-available, and Intima Bioscience apparently is not even registered to do business in the state in which it is headquartered. We need this information to effectively comment on the licenses.

Thanks,

Kathryn

On Tue, Sep 10, 2019 at 4:00 PM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Dear Ms. Ardizzone,

Answers to your questions are provided below.

Regards,

Andy

Andrew R. Burke, Ph.D.

Senior Technology Transfer Manager

National Cancer Institute

9609 Medical Center Drive, Rm 1E550

Rockville, MD 20850

Direct: (240) 276-5484

Email: andy.burke@nih.gov

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From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Monday, September 9, 2019 12:30 PM

To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>

Subject: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Dr. Burke:

Please answer the following questions related to Federal Register notice 84 FR 45503 regarding, "Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy."

1. At what stage of development are the inventions listed? Answer: Preclinical

a. If there has been a clinical trial, please list any NCT clinical trial numbers.

2. If the government has provided funding:

a. How much has been spent by the government on these trials? Answer: The technologies are preclinical.

- b. Please identify any NIH grant numbers.
 - c. Please confirm whether grants 5R21CA216652-02 and 1R21CA216652-01A1 are associated. Answer: Please direct this question to the University of Minnesota or consult NIH Reporter.
3. Please confirm or deny whether the license will “extend to the expiration of the last to expire of the Licensed Patent Rights” as provided in the NIH Model Exclusive Patent License Agreement. Answer: This has not yet been determined.
- a. If you deny #4, please state the duration of exclusivity.
4. Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559)?
5. According to the Federal Register notice, Intima Bioscience is “headquartered in New York.” According to the PCT applications PCT/US2016/044856, PCT/US2016/044858 and PCT/US2017/058615, Intima Bioscience has an address at 3 Columbus Circle New York, New York 10019. However, a search for the entity name “Intima Bioscience” using the NYS Department of State Division of Corporations database does not return any company with that name. A search for the entity name “Intima Capital” using the NYS Department of State Division of Corporations database does return a registered company with addresses in 3 Columbus Circle New York, New York 10019. Please confirm whether the prospective licensee is “Intima Bioscience” or “Intima Capital.” Answer: The applicant is Intima Bioscience, Inc.
6. Is the prospective licensee in this case the same company listed in the Federal Register notice 80 FR 59790, titled “Prospective Grant of Exclusive License: Development of Non-viral Adoptive Cell Transfer-based Immunotherapies (ACT) for the Treatment and Prophylaxis of Patients With Metastatic Cancer”? Answer: Yes, the applicant is the same.
- a. Was the exclusive license described in 80 FR 59790 executed? Answer: No
- b. If so, what is the rationale for granted additional exclusive rights to Intima Bioscience in a field of use that also relates to cancer?
7. How did the NIH determine that Intima Bioscience is an appropriate licensee? Who are the principals of the company? Answer: The preliminary determination was based on a review of the commercial development plan and supporting information submitted by the company in their application for license.
8. Does Intima Bioscience have a website? If so, please provide a link to their website. Answer: I am not aware of a website for Intima Bioscience, Inc.
- a. Note that “Intima Capital,” a company located in 3 Columbus Circle New York, New York and registered to do business there, does seem to have a website: <http://intimacapital.com/>
- b. Note also that a study performed by University of Minnesota Scientists Branden Moriarity and RS Ivor (co-inventors on the patent listed) in “Gene Engineering for Cancer Therapy” was funded by Intima Capital LLC.
- c. If Intima Capital and Intima Bioscience are related, what is the relationship? Answer: Please direct this question to the company.
9. Please confirm whether the following CRADA is associated with the licensed technology:
- a. CRADA No. C-058-2015/0, *Development and Evaluation of Intima Bioscience Proprietary Non-Viral Vectors for the Integration of Genes Encoding Mutation Specific T Cell Receptors that Have Been Identified Using NCI Proprietary Methods for the Identification of Lymphocytes and Receptors Specific for Mutated Cancer Antigens Expressed by the Autologous Cancer*
Answer: The patents and patent applications listed in 84 FR 45503 are not Subject Inventions of this or any NCI CRADA.
- b. If your answer to No. 6 is “No,” please identify any CRADAs associated with any of the subject inventions.

10. Did the NIH previously post this technology in the Federal Register under "Government Inventions available for licensing" or on the NIH's OTT Website's "Licensing Opportunities"? Answer: No

a.If "Yes," please provide a citation for the listing(s).

11. According to the Federal Register notice Intima Bioscience, Inc. is a co-owner of the listed patent documents. Why is the NIH proposing to license rights in patents/patent applications that are already co-owned by the prospective licensee? Why is the rationale for this? Answer: Because NIH wishes to grant an exclusive license to improve the chances that the technologies will be made available to the public.
12. How has NIH ensured that the grant and scope of exclusivity are no greater than reasonably necessary to incentivize Intima Bioscience to commercialize the licensed technology? Answer: As 37 CFR 404.7(a)(1)(ii) makes clear, consideration of any written objection(s) timely received in response to the notice provided in 84 FR 45503 is a necessary component of the determination required by 37 CFR 404.7(a)(1)(ii)(C). Since the 15-day notice period for this proposed license remains open, the final determination that 37 CFR 404.7(a)(1)(ii)(C) is satisfied has not been made.

Thank you in advance for your assistance in this matter.

Sincerely,

Kathryn Ardizzone and Luis Gil Abinader

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

--

Kathryn Ardizzone, Esq.

Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From: Vepa, Sury (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=25B6C29F123544738FCBAD51627B2D23-VEPAS]
Sent: 7/10/2018 7:06:35 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Portilla, Lili (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b03f548be224eb9b7b6167a32e9cc4a-portilll]
Subject: FW: Who runs Apexx Oncology?

See below another email from KEI.

b4,b5

Thanks,

Sury

Phone: 301-827-7181
Cell: b6
E-Mail: sury.vepa@nih.gov

From: James Love [mailto:james.love@keionline.org]
Sent: Tuesday, July 10, 2018 2:52 PM
To: Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov>
Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>
Subject: Re: Who runs Apexx Oncology?

So the license noticed in 2017 is being reconsidered in 2018?

Also, can you confirm that the company is a subsidiary of a company located in Switzerland?

On Tue, Jul 10, 2018 at 2:49 PM, Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov> wrote:

Yes.

Sury

Phone: 301-827-7181
Cell: b6
E-Mail: sury.vepa@nih.gov

REL0000024867

From: James Love [mailto:james.love@keionline.org]

Sent: Tuesday, July 10, 2018 2:32 PM

To: Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov>; Luis Gil Abinader <luis.gil.abinader@keionline.org>

Subject: Re: Who runs Apexx Oncology?

This is the same license and patents?

<https://www.keionline.org/24177>

On Tue, Jul 10, 2018 at 2:23 PM, Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov> wrote:

This is republication of the FR Notice published previously (82 FR 25295) and was necessitated because the GeneXion Oncology, Inc changed its name to Apexx Oncology. Thanks.

Sury Vepa

Phone: 301-827-7181

Cell: b6

E-Mail: sury.vepa@nih.gov

From: James Love [mailto:james.love@keionline.org]

Sent: Tuesday, July 10, 2018 1:16 PM

To: Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov>

Subject: Who runs Apexx Oncology?

--

REL0000024867

James Love. Knowledge Ecology International
<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,
twitter.com/jamie_love

--

James Love. Knowledge Ecology International
<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,
twitter.com/jamie_love

--

James Love. Knowledge Ecology International
<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,
twitter.com/jamie_love

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 9/16/2019 4:29:04 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Hi Mark,

Here's my response to KEI from September 12.

Thanks,

Andy

From: Burke, Andy (NIH/NCI) [E]
Sent: Thursday, September 12, 2019 4:26 PM
To: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Subject: RE: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Ms. Ardizzone,

Answers to your questions are provided below.

Regards,

Andy

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Thursday, September 12, 2019 1:38 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>
Subject: Re: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Thank you for your response, Dr. Burke.

I have an additional question about the licenses. The FR notice lists three NIH OTT Reference Numbers. As far as I understand, those numbers are assigned to an invention when one is disclosed by an NIH intramural researcher. Or, at the very least, each number pertains to its own invention. **Can you please confirm that three inventions would be covered by the license?** Answer: The number of patentably distinct inventions will be determined during prosecution at the relevant patent offices.

Also, I understand that it is part of NIH's licensing policy to publish licensing opportunity notices on its OTT website. When I searched the numbers listed on the search engine here: <https://www.ott.nih.gov/opportunities>, no results were returned. **Why is that?** Answer: Please see previous response in my email of September 10.

Thank you again for your time and attention to this matter.

Kathryn Ardizzone

REL0000024868

On Wed, Sep 11, 2019 at 4:45 PM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Dear Ms. Ardizzone,

Answers to your questions are provided below.

Regards,

Andy

From: kathryn ardizzone <kathrynardizzonekei@gmail.com>
Sent: Wednesday, September 11, 2019 2:29 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>
Subject: Re: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Dr. Burke:

Thank you for your response.

Given the lack of publicly-available data about the company (no website, no registration in NY, no officers or contact information for those officers listed in Delaware corporate records), how do you propose that KEI request this information directly from the company? Answer: The company's mailing address is publicly-available, as is a phone number. Please see, for example, <https://start.cortera.com/company/research/l6o5lxm2r/intima-bioscience-inc/>.

Also, please clarify why you are unable to release this information. Answer: Please see 37 CFR 404.14

Finally, please explain how the public can be ensured that Intima Bioscience, Inc. is an appropriate licensee, who can bring the invention to market, without even knowing who its principals are, and without the ability to contact them directly for that information.

Thank you,
Kathryn Ardizzone

REL0000024868

On Wed, Sep 11, 2019 at 1:40 PM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Dear Ms. Ardizzone,

I am unable to release this information. You may, however, request it directly from the company.

Regards,

Andy

From: kathryn ardizzone <kathrynardizzonekei@gmail.com>

Sent: Wednesday, September 11, 2019 12:59 PM

To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>

Subject: Re: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Thank you, Andy.

Can you please answer our question about Intima Bioscience's principals/list the members of its board of directors? We believe that is not too much to ask, considering that this information is not publicly-available, and Intima Bioscience apparently is not even registered to do business in the state in which it is headquartered. We need this information to effectively comment on the licenses.

Thanks,

Kathryn

On Tue, Sep 10, 2019 at 4:00 PM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Dear Ms. Ardizzone,

Answers to your questions are provided below.

REL0000024868

Regards,

Andy

Andrew R. Burke, Ph.D.

Senior Technology Transfer Manager

National Cancer Institute

9609 Medical Center Drive, Rm 1E550

Rockville, MD 20850

Direct: (240) 276-5484

Email: andy.burke@nih.gov

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From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Monday, September 9, 2019 12:30 PM

To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>

Subject: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Dr. Burke:

Please answer the following questions related to Federal Register notice 84 FR 45503 regarding, "Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy."

1. At what stage of development are the inventions listed? Answer: Preclinical
 - a. If there has been a clinical trial, please list any NCT clinical trial numbers.
2. If the government has provided funding:

- a. How much has been spent by the government on these trials? Answer: The technologies are preclinical.
 - b. Please identify any NIH grant numbers.
 - c. Please confirm whether grants 5R21CA216652-02 and 1R21CA216652-01A1 are associated. Answer: Please direct this question to the University of Minnesota or consult NIH Reporter.
3. Please confirm or deny whether the license will “extend to the expiration of the last to expire of the Licensed Patent Rights” as provided in the NIH Model Exclusive Patent License Agreement. Answer: This has not yet been determined.
 - a. If you deny #4, please state the duration of exclusivity.
4. Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559)?
5. According to the Federal Register notice, Intima Bioscience is “headquartered in New York.” According to the PCT applications PCT/US2016/044856, PCT/US2016/044858 and PCT/US2017/058615, Intima Bioscience has an address at 3 Columbus Circle New York, New York 10019. However, a search for the entity name “Intima Bioscience” using the NYS Department of State Division of Corporations database does not return any company with that name. A search for the entity name “Intima Capital” using the NYS Department of State Division of Corporations database does return a registered company with addresses in 3 Columbus Circle New York, New York 10019. Please confirm whether the prospective licensee is “Intima Bioscience” or “Intima Capital.” Answer: The applicant is Intima Bioscience, Inc.
6. Is the prospective licensee in this case the same company listed in the Federal Register notice 80 FR 59790, titled “Prospective Grant of Exclusive License: Development of Non-viral Adoptive Cell Transfer-based Immunotherapies (ACT) for the Treatment and Prophylaxis of Patients With Metastatic Cancer”? Answer: Yes, the applicant is the same.
 - a. Was the exclusive license described in 80 FR 59790 executed? Answer: No
 - b. If so, what is the rationale for granted additional exclusive rights to Intima Bioscience in a field of use that also relates to cancer?
7. How did the NIH determine that Intima Bioscience is an appropriate licensee? Who are the principals of the company? Answer: The preliminary determination was based on a review of the commercial development plan and supporting information submitted by the company in their application for license.
8. Does Intima Bioscience has a website? If so, please provide a link to their website. Answer: I am not aware of a website for Intima Bioscience, Inc.
 - a. Note that “Intima Capital,” a company located in 3 Columbus Circle New York, New York and registered to do business there, does seem to have a website: <http://intimacapital.com/>
 - b. Note also that a study performed by University of Minnesota Scientists Branden Moriarity and RS Ivor (co-inventors on the patent listed) in “Gene Engineering for Cancer Therapy” was funded by Intima Capital LLC.
 - c. If Intima Capital and Intima Bioscience are related, what is the relationship? Answer: Please direct this question to the company.
9. Please confirm whether the following CRADA is associated with the licensed technology:
 - a. CRADA No. C-058-2015/0, *Development and Evaluation of Intima Bioscience Proprietary Non-Viral Vectors for the Integration of Genes Encoding Mutation Specific T Cell Receptors that Have Been Identified Using NCI Proprietary Methods for the Identification of Lymphocytes and Receptors Specific for Mutated Cancer Antigens Expressed by the Autologous Cancer* Answer: The patents and patent applications listed in 84 FR 45503 are not Subject Inventions of this or any NCI CRADA.

- b. If your answer to No. 6 is "No," please identify any CRADAs associated with any of the subject inventions.
10. Did the NIH previously post this technology in the Federal Register under "Government Inventions available for licensing" or on the NIH's OTT Website's "Licensing Opportunities"? Answer: No
- a. If "Yes," please provide a citation for the listing(s).
11. According to the Federal Register notice Intima Bioscience, Inc. is a co-owner of the listed patent documents. Why is the NIH proposing to license rights in patents/patent applications that are already co-owned by the prospective licensee? Why is the rationale for this? Answer: Because NIH wishes to grant an exclusive license to improve the chances that the technologies will be made available to the public.
12. How has NIH ensured that the grant and scope of exclusivity are no greater than reasonably necessary to incentivize Intima Bioscience to commercialize the licensed technology? Answer: As 37 CFR 404.7(a)(1)(ii) makes clear, consideration of any written objection(s) timely received in response to the notice provided in 84 FR 45503 is a necessary component of the determination required by 37 CFR 404.7(a)(1)(ii)(C). Since the 15-day notice period for this proposed license remains open, the final determination that 37 CFR 404.7(a)(1)(ii)(C) is satisfied has not been made.

Thank you in advance for your assistance in this matter.

Sincerely,

Kathryn Ardizzone and Luis Gil Abinader

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

--

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Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

From: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIH/OD/CN=RECIPIENTS/CN=HAMMERSLAA]
Sent: 2/17/2016 11:59:43 AM
To: Berkley, Dale (NIH/OD) [E] [/O=NIH/OU=NIH/OD/CN=RECIPIENTS/CN=BERKLEYD]; Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/OD/CN=RECIPIENTS/CN=ROHRBAUM]; Hruszkewycz, Andrew (NIH/NCI) [E] [/O=NIH/OU=NIH/OD/CN=RECIPIENTS/CN=HRUSZKEA]; Muroff, Julie (NIH/OD) [E] [/O=NIH/OU=NIH/OD/CN=RECIPIENTS/CN=MUROFFJ]
Subject: RE: KEI 01/14/2014 Bayh-Dole March-In Request

Good Morning Dale:

b5

b5

Thanks everyone. Soon you will receive an outlook message.

Ann

From: Berkley, Dale (NIH/OD) [E]
Sent: Tuesday, February 16, 2016 4:30 PM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Hruszkewycz, Andrew (NIH/NCI) [E] <hruskeaa@mail.nih.gov>; Muroff, Julie (NIH/OD) [E] <muroffj@od.nih.gov>
Subject: RE: KEI 01/14/2014 Bayh-Dole March-In Request

I'm available at 4pm on the 23rd.

b5

Thanks, Dale

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

This message is intended for the exclusive use of the recipient(s) named above. It may contain information that is PROTECTED or PRIVILEGED, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information.

From: Hammersla, Ann (NIH/OD) [E]
Sent: Tuesday, February 16, 2016 4:10 PM
To: Berkley, Dale (NIH/OD) [E]; Rohrbaugh, Mark (NIH/OD) [E]; Hruszkewycz, Andrew (NIH/NCI) [E]; Muroff, Julie (NIH/OD) [E]
Subject: RE: KEI 01/14/2014 Bayh-Dole March-In Request

It appears that 2/23 at 1:00 does not work for everyone. How about 4:00 on 2/23rd? Can you make it then?

REL0000024870

Other NIH march-in decisions: Were on the OTT website and it appears this afternoon they have been taken down. I will see what I can do to find a current link to them. Mark – do you know where OTT included these decisions as well as other NIH specific decisions?

Links to:

Knowledge Ecology International : <http://www.keionline.org/>

Information on KEI's website regarding this march-in request: <http://www.keionline.org/node/2412>

Ann

From: Hammersla, Ann (NIH/OD) [E]

Sent: Tuesday, February 16, 2016 1:30 PM

To: Hruszkewycz, Andrew (NIH/NCI) [E]; Rohrbaugh, Mark (NIH/OD) [E]; Berkley, Dale (NIH/OD) [E]; Muroff, Julie (NIH/OD) [E]

Cc: Bulls, Michelle G. (NIH/OD) [E]; Helfer, Jacqueline (NIH/OD) [C]; Cooper, Scott (NIH/OD) [E]

Subject: KEI 01/14/2014 Bayh-Dole March-In Request

Good Morning Andrew, Mark, Dale and Julie:

I am writing to ask each of you to assist OPERA/DEITR in reviewing and responding to the attached march-in request and the request to use the government's royalty-free license from Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (ACT). I would like to arrange for a call of all of us on February 23 at 1:30. Are you available?

The KEI request is to use the government's rights on 3 inventions that were jointly supported by NIH and the Army. The inventions and subsequent patents are used for the prostate cancer drug (enzalutamide) marketed under the brand name of Xtandi by Japan-based Astellas Pharma. All 3 patents identify CA 092131 as funding the underlying research for these inventions and patents.

I have attached a summary of march-in and the government's royalty-free license. I have been in contact with the Army and it has requested to participate in our discussions which we can discuss when we meet.

The summary of KEI's request is:

"Xtandi is an expensive drug everywhere, indeed so expensive that access is extremely limited in many countries. But, based upon research, the prices in the United States are far higher than any other country in the world, despite the fact that the critical research benefited from U.S. taxpayer funded grants from the NIH and DOD."

Mark – could you please send to everyone NIH's recent response or draft response to the Congressional inquiry about the use of NIH's march-in authority and the pricing of the drugs?

OGC: I am not sure if one or both of you will be participating – just let me know.

Please let me know if you are available on 2/23rd at 1:30.

Ann

REL0000024870

--

Ann M. Hammersla, J.D.

Director

Division of Extramural Inventions and Technology Resources

Office of Policy for Extramural Research Administration

Director, Division of Policy, Office of Technology Transfer

Rockledge 1, Suite 310

6705 Rockledge Drive

Bethesda, Maryland 20892-7974

PHONE: 301-451-4235

From: Berkson, Laura (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAMIANOLD]
Sent: 6/20/2016 8:11:40 PM
To: Baker, Rebecca (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Bakerrg]; Hallett, Adrienne (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Hallettaa07c]; Myles, Renate (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=recipients/cn=mylesr]; Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]; Culhane, Ned (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=recipients/cn=culhane]; Allen-Gifford, Patrice (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Allengiffordpldc3]; Higgins, Lauren (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=HigginsL]
Subject: NIH rejects petition to override patent on pricey prostate cancer drug

FYI, there is an article in STAT about the Xtandi decision: <https://www.statnews.com/pharmalot/2016/06/20/nih-rejects-patent-petition/>. It links to a pdf of the letter.

NIH rejects petition to override patent on pricey prostate cancer drug



NIH Director Dr. Francis Collins

By ED SILVERMAN @Pharmadot
JUNE 20, 2016

After five months of deliberation, the US National Institutes of Health on Monday rejected a request by several consumer groups to override the patent on a prostate cancer drug because the medicine is more expensive in the United States than elsewhere. And one of the consumer groups plans to seek an appeal.

Last January, the groups petitioned the NIH to take this step, which is known as a march-in right, to help US patients because federally funded research was used to create Xtandi. The drug is sold by Astellas Pharma and has an average wholesale price in the United States of more than \$129,000, about two to four times more than what other high-income countries are paying, according to the consumer groups.

Under federal law, a march-in right allows an agency that funds private research to require a drug maker to license its patent to another party in order to “alleviate health and safety needs which are not being reasonably satisfied” or when the benefits of a drug are not available on “reasonable terms.” The drug was developed at the University of California, Los Angeles, with grants from NIH and the US Department of Defense. The school licensed the drug to Medivation, which struck a marketing deal with Astellas.

However, the NIH denied the petition because there was no information to suggest that Xtandi is or will be in short supply, according to a letter sent on Monday by NIH Director Dr. Francis Collins to Knowledge Ecology International, one of the consumer groups. The agency, which has rarely granted such petitions, noted that the litmus test used in one previous case was whether there were sufficient supplies of the medicine for which a petition was sought.

In a statement, the consumer groups argued the NIH “did not evaluate evidence provided that Astellas charges US residents prices that are far higher than those available to non-US consumers, and that price discrimination against US residents is not consistent with making the product ‘available to the public on reasonable terms,’” as required by federal law.

They also maintained the NIH failed to address evidence that “the unreasonably high price for Xtandi limits patient access, places the drugs on restrictive formularies, causes strain to health care budgets, and requires patients to pay unreasonably high coinsurance and copayments,” all of which justify the use of march-in rights.

They added that the NIH ignored its ability to issue a nonexclusive, royalty-free license to allow Xtandi to be manufactured for use by the federal government. Knowledge Ecology legal and policy counselor Andrew Goldman said there is no precondition about supplies and the NIH is wrong to assert that there is no limit on “excessive pricing” in order to grant a march-in right.

“This is contrary to the legislative intent of the law, and sends a terrible signal about the government’s willingness to confront the high drug prices through available legal mechanisms,” he said.

The consumer group plans to submit an appeal to US Secretary of Health and Human Services Sylvia Burwell and said it will base its appeal on the NIH’s “flawed legal rationale” about the use of march-in rights and “its lack of analysis concerning its refusal to use a royalty-free license.” The group added that it plans to refile this case after a new president takes office next year if the HHS declines its appeal.

As part of its effort, Knowledge Ecology two months ago solicited Biolyse, a small Canadian drug company, to make Xtandi. The drug maker maintained it could supply a version for \$3 per 40-milligram tablet, compared with the \$69.41 that Medicare paid in 2014. Biolyse hoped to be able to supply its version in three years. We left word with a company spokesman and will pass along any reply.

An Astellas spokesman wrote us to say that the company is “pleased that the NIH has concluded that Xtandi is broadly available to patients, and we are committed to continuing our work with our diverse stakeholders to provide patients with affordable access to our medicines.”

The rejection is not a surprise, though.

Two months ago, the Obama administration rejected a request from dozens of congressional Democrats, who call themselves the Affordable Drug Pricing Task Force, to develop guidelines that would require drug makers to license their patents and put a lid on “price gouging.” They argued the NIH should be more aggressively granting march-in rights in light of the high price of medicine.

At the time, Burwell noted such decisions are made on a case-by-case basis. The NIH previously considered using its march-in authority concerning drug pricing in 2004 and 2013, but determined statutory requirements were not met. Two of those instances involved the Norvir AIDS medicine that was marketed by Abbott Laboratories — now owned by AbbVie — and the Xalatan glaucoma treatment sold by Pfizer.

In response, several lawmakers, including presidential aspirant Bernie Sanders, said they would seek a hearing about NIH use of march-in rights, but that never took place.

From: Myles, Renate (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=MYLESR]
Sent: 6/20/2016 8:50:46 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: Re: AJOY?: NIH rejects petition to override patent on pricey prostate cancer drug

b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, June 20, 2016 4:47 PM
To: Myles, Renate (NIH/OD) [E]
Subject: FW: AJOY?: NIH rejects petition to override patent on pricey prostate cancer drug

b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, June 20, 2016 4:43 PM
To: Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>
Cc: Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: RE: AJOY?: NIH rejects petition to override patent on pricey prostate cancer drug

b5

From: Kassilke, Deborah (NIH/OD) [E]
Sent: Monday, June 20, 2016 4:39 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Subject: FW: AJOY?: NIH rejects petition to override patent on pricey prostate cancer drug

b5

From: Prabhu, Ajoy (NIH/OD) [E]
Sent: Monday, June 20, 2016 4:38 PM
To: Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>
Cc: Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Subject: Re: AJOY?: NIH rejects petition to override patent on pricey prostate cancer drug

b5

Ajoy

REL0000024872

From: "Kassilke, Deborah (NIH/OD) [E]" <deborah.kassilke@nih.gov>
Date: Monday, June 20, 2016 at 4:34 PM
To: Ajoy Prabhu <aprabhu@od.nih.gov>
Cc: Karen Rogers <RogersK@od.nih.gov>
Subject: RE: AJOY?: NIH rejects petition to override patent on pricey prostate cancer drug

Ajoy -

b5

b5

From: Prabhu, Ajoy (NIH/OD) [E]
Sent: Monday, June 20, 2016 4:29 PM
To: Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>
Cc: Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Subject: Re: AJOY?: NIH rejects petition to override patent on pricey prostate cancer drug

Sorry about the delay. It is up on the page—

<http://www.ott.nih.gov/policies-reports>

Exact URL is: http://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/Final_Response_Goldman_6.20.2016.pdf

Ajoy

From: "Kassilke, Deborah (NIH/OD) [E]" <deborah.kassilke@nih.gov>
Date: Monday, June 20, 2016 at 4:23 PM
To: Ajoy Prabhu <aprabhu@od.nih.gov>
Cc: Karen Rogers <RogersK@od.nih.gov>
Subject: RE: AJOY?: NIH rejects petition to override patent on pricey prostate cancer drug

b5

From: Prabhu, Ajoy (NIH/OD) [E]
Sent: Monday, June 20, 2016 4:23 PM
To: Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>
Cc: Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>
Subject: Re: AJOY?: NIH rejects petition to override patent on pricey prostate cancer drug

Not at all. I will certainly make sure that it is up shortly. I had to check with Promet about the security update that was scheduled over the weekend.

Ajoy

From: "Kassilke, Deborah (NIH/OD) [E]" <deborah.kassilke@nih.gov>
Date: Monday, June 20, 2016 at 4:20 PM
To: Ajoy Prabhu <aprabhu@od.nih.gov>
Cc: Karen Rogers <RogersK@od.nih.gov>
Subject: AJOY?: NIH rejects petition to override patent on pricey prostate cancer drug

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, June 20, 2016 4:20 PM
To: Rogers, Karen (NIH/OD) [E] <RogersK@od.nih.gov>; Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>
Subject: FW: NIH rejects petition to override patent on pricey prostate cancer drug

Sorry to bug you.. would be great to get the decision up today.

From: Berkson, Laura (NIH/OD) [E]
Sent: Monday, June 20, 2016 4:12 PM
To: Baker, Rebecca (NIH/OD) [E] <bakerrg@od.nih.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Culhane, Ned (NIH/OD) [E] <culhane@mail.nih.gov>; Allen-Gifford, Patrice (NIH/OD) [E] <patrice.allen-gifford@nih.gov>; Higgins, Lauren (NIH/OD) [E] <HigginsL@OD.NIH.GOV>
Subject: NIH rejects petition to override patent on pricey prostate cancer drug

FYI, there is an article in STAT about the Xtandi decision: <https://www.statnews.com/pharmalot/2016/06/20/nih-rejects-patent-petition/>. It links to a pdf of the letter.

NIH rejects petition to override patent on pricey prostate cancer drug



NIH Director Dr. Francis Collins

By ED SILVERMAN @Pharmalot
JUNE 20, 2016

After five months of deliberation, the US National Institutes of Health on Monday rejected a request by several consumer groups to override the patent on a prostate cancer drug because the medicine is more expensive in the United States than elsewhere. And one of the consumer groups plans to seek an appeal.

Last January, the groups petitioned the NIH to take this step, which is known as a march-in right, to help US patients because federally funded research was used to create Xtandi. The drug is sold by Astellas Pharma and has an average wholesale price in the United States of more than \$129,000, about two to four times more than what other high-income countries are paying, according to the consumer groups.

Under federal law, a march-in right allows an agency that funds private research to require a drug maker to license its patent to another party in order to “alleviate health and safety needs which are not being reasonably satisfied” or when the benefits of a drug are not available on “reasonable terms.” The drug was developed at the University of California, Los Angeles, with grants from NIH and the US Department of Defense. The school licensed the drug to Medivation, which struck a marketing deal with Astellas.

However, the NIH denied the petition because there was no information to suggest that Xtandi is or will be in short supply, according to a letter sent on Monday by NIH Director Dr. Francis Collins to Knowledge Ecology International, one of the consumer groups. The agency, which has rarely granted such petitions, noted that the litmus test used in one previous case was whether there were sufficient supplies of the medicine for which a petition was sought.

In a statement, the consumer groups argued the NIH “did not evaluate evidence provided that Astellas charges US residents prices that are far higher than those available to non-US consumers, and that price discrimination against US residents is not consistent with making the product ‘available to the public on reasonable terms,’” as required by federal law.

They also maintained the NIH failed to address evidence that “the unreasonably high price for Xtandi limits patient access, places the drugs on restrictive formularies, causes strain to health care budgets, and requires patients to pay unreasonably high coinsurance and copayments,” all of which justify the use of march-in rights.

They added that the NIH ignored its ability to issue a nonexclusive, royalty-free license to allow Xtandi to be manufactured for use by the federal government. Knowledge Ecology legal and policy counselor Andrew Goldman said there is no precondition about supplies and the NIH is wrong to assert that there is no limit on “excessive pricing” in order to grant a march-in right.

“This is contrary to the legislative intent of the law, and sends a terrible signal about the government’s willingness to confront the high drug prices through available legal mechanisms,” he said.

The consumer group plans to submit an appeal to US Secretary of Health and Human Services Sylvia Burwell and said it will base its appeal on the NIH’s “flawed legal rationale” about the use of march-in rights and “its lack of analysis concerning its refusal to use a royalty-free license.” The group added that it plans to refile this case after a new president takes office next year if the HHS declines its appeal.

As part of its effort, Knowledge Ecology two months ago solicited Biolyse, a small Canadian drug company, to make Xtandi. The drug maker maintained it could supply a version for \$3 per 40-milligram tablet, compared with the \$69.41 that Medicare paid in 2014. Biolyse hoped to be able to supply its version in three years. We left word with a company spokesman and will pass along any reply.

An Astellas spokesman wrote us to say that the company is “pleased that the NIH has concluded that Xtandi is broadly available to patients, and we are committed to continuing our work with our diverse stakeholders to provide patients with affordable access to our medicines.”

The rejection is not a surprise, though.

Two months ago, the Obama administration rejected a request from dozens of congressional Democrats, who call themselves the Affordable Drug Pricing Task Force, to develop guidelines that would require drug makers to license their patents and put a lid on “price gouging.” They argued the NIH should be more aggressively granting march-in rights in light of the high price of medicine.

At the time, Burwell noted such decisions are made on a case-by-case basis. The NIH previously considered using its march-in authority concerning drug pricing in 2004 and 2013, but determined statutory requirements were not met. Two of those instances involved the Norvir AIDS medicine that was marketed by Abbott Laboratories — now owned by AbbVie — and the Xalatan glaucoma treatment sold by Pfizer.

In response, several lawmakers, including presidential aspirant Bernie Sanders, said they would seek a hearing about NIH use of march-in rights, but that never took place.

From: Dodson, Sara (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DODSONSE]
Sent: 6/29/2016 1:52:31 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=OD/cn=ROHRBAUM]; Rosema, Laura (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Rosemals01d]
Subject: RE: Reminder: NIH Conference Call Today at 11AM (Call-in Information and Agenda in Email)

I've got another call at 11:30, but I can call in at 11.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, June 29, 2016 9:50 AM
To: Dodson, Sara (NIH/OD) [E] <sara.dodson@nih.gov>; Rosema, Laura (NIH/OD) [E] <laura.rosema@nih.gov>
Subject: FW: Reminder: NIH Conference Call Today at 11AM (Call-in Information and Agenda in Email)

Are either of you available just to listen in?

From: Zack Struver [mailto:zack.struver@keionline.org]
Sent: Wednesday, June 29, 2016 9:42 AM
To: James Love <james.love@keionline.org>; Andrew S. Goldman <andrew.goldman@keionline.org>; Manon Ress <manon.ress@keionline.org>; Diane Singhroy <diane.singhroy@keionline.org>; Claire Cassedy <claire.cassedy@keionline.org>; Elizabeth Rajasingh <elizabeth.rajasingh@keionline.org>; Thiru Balasubramaniam <thiru@keionline.org>
Subject: Reminder: NIH Conference Call Today at 11AM (Call-in Information and Agenda in Email)

This is a reminder that KEI will be hosting a conference call at 11:00 A.M. today to brief interested stakeholders and the press on issues related to NIH patent policy, including the recent decision in KEI's Xtandi petition (additional background here: <http://keionline.org/xtandi>), the grant of exclusive licenses on government-owned inventions (<http://keionline.org/nih-licenses>), and transparency of decision-making at NIH more broadly.

Please note that this call will be on the record, and that by participating you consent to be recorded.

The agenda is here: <http://keionline.org/node/2608>

The call-in information is below:

Number: b6
Access Code: b6

(Please let me know if you need a non-U.S. dial-in number and I will be happy to provide it.)

--
Zack Struver, Communications and Research Associate
Knowledge Ecology International
zack.struver@keionline.org
Twitter: [@zstruver](https://twitter.com/zstruver)
Office: +1 (202) 332-2670 Cell: +1 (914) 582-1428
keionline.org

REL0000024873

From: Fine, Amanda (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FINEAB]
Sent: 4/26/2016 6:17:06 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
CC: Myles, Renate (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=RECIPIENTS/CN=MYLES]
Subject: FW: Question from St. Catharines Standard in Canada
Attachments: Biolyse Pharma letter (1).pdf

Hi Mark-

Please see the below inquiry we received on Xtandi related issue.

b5

b5

but wanted to check with you to get your input. In regards to

b5

b5

Thanks in advance for your help,
Amanda

From: Walter, Karena [mailto:KWalter@postmedia.com]
Sent: Tuesday, April 26, 2016 11:44 AM
To: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: Question from St. Catharines Standard in Canada

Hi Amanda,

I'm a reporter at the St. Catharines Standard newspaper in Ontario Canada covering the Niagara Region.

I'm writing about the prostate cancer drug Xtandi and a local connection.

I understand KEI and UACT asked the National Institutes of Health to override the patent for Xtandi in January.

It's my understanding that drug maker Biolyse Pharma in St. Catharines was approached by KEI about whether it's capable and willing to produce a generic version if it was allowed to do so.

Biolyse says it can supply a generic version of enzalutamide (brand name Xtandi) for \$3 per tablet if it's allowed. The president of Biolyse sent a letter to the Centers for Medicare and Medicaid Services on Friday.

I'm contacting you for NIH's position... Is there a chance Biolyse would be allowed to do this? Has NIH responded to the letters from KEI? Was there a response to the March 28 letter by Bernie Sanders and other lawmakers requesting a hearing about the drug?

Any information you can provide would be greatly appreciated.

Thank you,
Karena Walter

Karena Walter
Reporter, The Standard
10-1 St. Paul St.
St. Catharines, ON
L2R7L4
905.684.7251 ext. 581148
kwalter@postmedia.com
[@karena_standard](#)

REL0000024875

From: Baker, Rebecca (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BAKERRG]
Sent: 4/13/2016 3:28:15 PM
To: Marshall, Lisa (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=SchwartzL]; Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
CC: Plude, Denise (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=parksde]; Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: RE: Xtandi letters are cleared/signed

Thanks Lisa,

We informed the Department, and they wanted to share our decision with the White House before we send. I will let everyone know when we receive the green light.

Best,
Rebecca

From: Marshall, Lisa (NIH/OD) [E]
Sent: Wednesday, April 13, 2016 11:26 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Baker, Rebecca (NIH/OD) [E] <bakerrg@od.nih.gov>
Cc: Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: RE: Xtandi letters are cleared/signed

Attached is the final letter signed by Dr. Collins. I just talked to Rebecca, who told me to hold until she circles around with the Department. Once I get the okay from her, I will email response to Mr. Goldman. In addition, once the Secretary has signed the response to congressional members, I'll get a copy of that to you as well. Thanks, Lisa

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, April 13, 2016 10:31 AM
To: Marshall, Lisa (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]
Cc: Plude, Denise (NIH/OD) [E]; Hammersla, Ann (NIH/OD) [E]
Subject: RE: Xtandi letters are cleared/signed

Rebecca:

I didn't think KH wanted to hold off on the letter to KEI on march-in, correct?
Could you send Ann and me the final letter from FC, please.

Mark

From: Marshall, Lisa (NIH/OD) [E]
Sent: Wednesday, April 13, 2016 9:04 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Baker, Rebecca (NIH/OD) [E] <bakerrg@od.nih.gov>
Cc: Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov>
Subject: Xtandi letters are cleared/signed
Importance: High

Good morning,

REL0000024880

Drs. Collins, Tabak, and Hudson have cleared the response for the Secretary's signature (and the draft will be transmitted to the Department this morning). Dr. Collins also signed the letter to Andrew Goldman, with Knowledge Ecology International. I think you wanted to hold off on emailing/ mailing this letter (you wanted to [redacted] **b5**

[redacted] **b5**
Collins response to Mr. Goldman? Many thanks, Lisa

Will you please let me know when it's okay to send Dr.

From: Dodson, Sara (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DODSONSE]
Sent: 6/29/2016 4:09:59 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=OD/cn=ROHRBAUM]; Rosema, Laura (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Rosemals01d]
Subject: RE: Reminder: NIH Conference Call Today at 11AM (Call-in Information and Agenda in Email)

Hi Mark and Laura,

Sharing my notes from the KEI call this am:

- Jamie Love (KEI) started the call
- KEI has filed objections to 18 exclusive licenses so far this year; public comment to NIH
- Xtandi update –
 - Petition filed in Jan 2016 (march-in rights or non-exclusive license rights)
 - FC's letter was very short, was not a serious response; it's not clear what data or evidence NIH considered in its decision; only cited decision re: march in, ignored non-exclusive license right; problems with citing short supply issue – it is not a pre-condition of gov use (sec 202) and march-in also does not have to be directly tied to supply issues; NIH response did not acknowledge any of the data that KEI supplied; a real condition is “reasonable terms” and NIH did not address/come to a conclusion on whether Xtandi pricing is reasonable; KEI provided data that insurers are tiering coverage and access/utilization on SES and racial lines is skewed; KEI additionally provided evidence from one mfg (Biolease?) that they would sell at \$3/pill
 - NIH has consistently done things behind the scenes. This was the shortest rejection they've ever seen. NIH has never granted a march-in request. They know that FC had personal convos with WH staff that he wasn't concerned about the specific conditions around Xtandi, just that it would set a bad precedent.
 - KEI plans to re-file in 2017 under a new president (and maybe figure out if they can get the HHS Sec to issue the decision instead).
- Other KEI efforts re: NIH-patented inventions and executed licenses
 - Non-transparent process: There is very little public info on the licenses NIH issues to companies; NIH will not disclose much info on licenses; KEI would have to sign a non-disclosure agreement to see more info; Calls often remain unanswered
 - Comments are based on Sec 35 USC209C1, 37CFR 404.7A1I – fed granting of an exclusive license; scope of exclusivity cannot be greater than is “reasonable necessary” and “benefits are available to the public on reasonable terms”
 - KEI is arguing that a number of high-priced drugs are not available on “reasonable terms”
 - In the case of the RSV vaccine – NIH spent 25 years on it; licensed to Sanofi; NIH will not give any info on the terms of the license; KEI has suggested language to be added to the license in order to protect pricing in U.S.
- Aaron Kesselheim, Assoc Prof of Medicine, Harvard University
 - Recently published paper in Nature Medicine re: Xtandi license and other drugs; they discuss a mechanism by which a generic mfg could apply directly to FDA; there might be an opening to side-step NIH
 - Gov patent use alternative – gov is allowed to appropriate an invention in exchange of reasonable compensation; They argue that gov could use this for Hep C drugs
- Mickey Davis
 - It's not surprising that NIH has never granted march-in
 - NIH has never cited language in the statute in their decisions/responses – it might form some hook for appellate purposes
 - The courts don't want to get involved in march-in either; courts are treating this as being discretionary by the government, but there may be opportunities to force the issue in the courts on the basis that gov has never cited “reasonable terms” in decisions

- Rachel Sacks, Assoc Prof of Law, Wash U
 - Xtandi – NIH does not want to touch pricing; Congress could make it clear that prices are a relevant criterion but Congress is not likely to force the issue; Limits of march-in rights to apply price-lowering pressures – all of the patents have to be held by gov; this is the perfect time to bring KEI petition; based on statutory provisions, it's not clear whether there is an obligation for NIH to be more transparent about these decisions – this could be a specific question that could be addressed in court; may also be able to challenge on grounds that NIH should disclose more about what they do with the royalties;
 - Jamie Love talked about COI – NIH scientists who receive royalties benefit from high-priced drugs; this is a massive licensing operation by NIH and it's secret
- Merit Davey, UAEM (Universities Allied for Essential Medicines)
 - Work to ensure that life-saving meds are available to all, esp. if grounded in university R&D
 - Appalled by NIH response; NIH has the opportunity to make meds more broadly available; choosing share-holders over patients
 - UAEM's plans – will lobby President to issue exec order to include stricter conditions in grant awards re: licensing terms; will continue to lobby future NIH director to exercise march-in
 - Jamie Love – in the Xtandi case, the Canadian biotech co. was seeking to provide low-priced Xtandi to South Africa, so NIH decision doesn't just affect U.S. citizens
- Phillip ?
 - His group asked NIH to exercise authority to issue licenses to international orgs and foreign govs royalty-free (e.g., Gardasil, sickle-cell txs); NIH has great power to do significant things around the world, and they are not making use
 - Gov has the right under law now to issue new licenses for any gov-provided service (e.g., use in prisons, VA, CMS, etc)
 - Jamie Love – the uncertainty of what constitutes “reasonable compensation” has been a major disincentive for the gov to exercise; Sen Sanders has a bill that is aimed to address
- Dan someone from BuzzFeed – what is NIH's perspective? Is NIH too cozy with Pharma?
 - Jamie Love – primary issue is that NIH sees their job on the product development side, not the pricing – NIH does not think it's part of their mission; second is that NIH directly profits from high-priced drugs (NIH scientists can get \$100-\$200k more a year); and they socialize a lot with people in Pharma; they don't get pressure from WH, OSTP, HHS, CMS, etc.
 - Why is CMS not pressuring NIH? Jamie Love says the defense across the gov is that the main policy is being set by the WH and they are pro Pharma; NIH is almost a separate fiefdom from HHS; It's going to depend on the next president
- Someone from Johns Hopkins asked about trends in NIH funding for Pharma R&D – seeing more and more public private partnerships; may make it more difficult for Universities to rally behind these issues due to personal interest
- March 2016 law on “Defend Trade Secrets” – will that make it harder for reform? Probably not, no provision re: fed gov.

From: Rohrbaugh, Mark (NIH/OD) [E]

Sent: Wednesday, June 29, 2016 9:50 AM

To: Dodson, Sara (NIH/OD) [E] <sara.dodson@nih.gov>; Rosema, Laura (NIH/OD) [E] <laura.rosema@nih.gov>

Subject: FW: Reminder: NIH Conference Call Today at 11AM (Call-in Information and Agenda in Email)

Are either of you available just to listen in?

From: Zack Struver [mailto:zack.struver@keionline.org]

Sent: Wednesday, June 29, 2016 9:42 AM

To: James Love <james.love@keionline.org>; Andrew S. Goldman <andrew.goldman@keionline.org>; Manon Ress <manon.ress@keionline.org>; Diane Singhroy <diane.singhroy@keionline.org>; Claire Cassedy

<claire.cassedy@keionline.org>; Elizabeth Rajasingh <elizabeth.rajasingh@keionline.org>; Thiru Balasubramaniam <thiru@keionline.org>

Subject: Reminder: NIH Conference Call Today at 11AM (Call-in Information and Agenda in Email)

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The agenda is here: <http://keionline.org/node/2608>

The call-in information is below:

Number: b6
Access Code: b6

(Please let me know if you need a non-U.S. dial-in number and I will be happy to provide it.)

--

Zack Struver, Communications and Research Associate
Knowledge Ecology International
zack.struver@keionline.org
Twitter: [@zstruver](https://twitter.com/zstruver)
Office: +1 (202) 332-2670 Cell: +1 (914) 582-1428
keionline.org

From: Kukic, Ira (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DF851C54F7714BC6A88567CCFA9CF62B-KUKICI2]
Sent: 11/1/2018 3:49:29 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: accomplishments

Great, thanks!

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, November 01, 2018 11:49 AM
To: Kukic, Ira (NIH/OD) [E] <ira.kukic@nih.gov>
Subject: accomplishments

b5, b6

Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer
Director, Division of Technology Transfer and Innovation Policy
Office of Science Policy
Office of the Director
National Institutes of Health

From: Frisbie, Suzanne (NIH/NIAID) [E] [/O=NIH/OU=NIHEXCHANGE/CN=NCI/CN=FRISBIES]
Sent: 3/7/2016 6:07:30 PM
To: Frisbie, Suzanne (NIH/NIAID) [E] [/O=NIH/OU=Nihexchange/cn=nci/cn=frisbies]; Williams, Richard (NIH/NIAID) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIAID/cn=RWILLIAMS]; Lambert, Richard (NIH/NIAID) [C] [/O=NIH/OU=NIHEXCHANGE/cn=NIAID/cn=LAMBERTR]; Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
CC: Mowatt, Michael (NIH/NIAID) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIAID/cn=MMOWATT]
Subject: Response to KEI
Location: Phone Call/6D40
Start: 3/8/2016 3:00:00 PM
End: 3/8/2016 4:00:00 PM
Show Time As: Busy

Recurrence: (none)

Required Attendees: Williams, Richard (NIH/NIAID) [E]; Lambert, Richard (NIH/NIAID) [C]; Rohrbaugh, Mark (NIH/OD) [E]
Optional Attendees: Mowatt, Michael (NIH/NIAID) [E]

Dial-In Number: b6
Participant Code: b6

From: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HAMMERSLAA]
Sent: 10/17/2016 6:16:04 PM
To: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]; Bleimund, Emily (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Bleimund.Emily.OS]; Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]

Subject: Discussion re KEI and meeting
Location: Telephone Conference or in AH's Office Rockledge 1

Start: 10/19/2016 2:00:00 PM
End: 10/19/2016 3:00:00 PM
Show Time As: Busy

Required Attendees: Bleimund, Emily (OS/OGA); Rohrbaugh, Mark (NIH/OD) [E]

From: Wolinetz, Carrie (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=WOLINETZCDC9A]
Sent: 10/28/2016 1:06:01 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wolinetzcdc9a]; Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]

Subject: Meeting/Call re Xtandi

Attachments: meeting request re Xtandi

Location: Dial: b6 PC: b6 Mobile friending: b6

Start: 10/31/2016 4:15:00 PM

End: 10/31/2016 4:45:00 PM

Show Time As: Busy

Required Attendees: Rohrbaugh, Mark (NIH/OD) [E]



meeting request re
Xtandi

From: Baker, Rebecca (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BAKERRG]
Sent: 10/27/2016 9:59:35 PM
To: Hardesty, Rebecca (NIH/OD) [C] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Hardestyrs2ae]
CC: Schulke, Hilda (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=OD/cn=schulkeh]
Subject: meeting request re Xtandi

Hi Rebecca,

Kathy would like a quick 15 minute meeting to discuss KEI and Xtandi developments. Could we find a time tomorrow or Monday that would work with Carrie and Kathy? We'd also like Mike Rohrbaugh to join.

Copying Hilda to help with Kathy's schedule.

Thanks,
Rebecca

Rebecca Baker, Ph.D.
Science Policy Analyst
Office of the Director
National Institutes of Health
Bethesda, MD 20892
Phone: 301-402-1994
rebecca.baker@nih.gov

From: Vepa, Sury (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=25B6C29F123544738FCBAD51627B2D23-VEPAS]
Sent: 7/11/2018 3:02:47 PM
To: Vepa, Sury (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25b6c29f123544738fcbad51627b2d23-vepas]; Portilla, Lili (NIH/NCATS) [E] [portilll@mail.nih.gov]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: Response to Knowledge Ecology International (KEI)
Attachments: RE: Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors Useful for Treating Cancer to Apexx Oncology. Notice for comment published in 83 FR 29562.
Location: Mark please call [b6]
Start: 7/11/2018 7:30:00 PM
End: 7/11/2018 8:30:00 PM
Show Time As: Busy

Required Attendees: Portilla, Lili (NIH/NCATS) [E]; Rohrbaugh, Mark (NIH/OD) [E]



RE: Prospective
Grant of Exclusiv...

From: Vepa, Sury (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=25B6C29F123544738FCBAD51627B2D23-VEPAS]
Sent: 7/11/2018 2:26:28 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Portilla, Lili (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b03f548be224eb9b7b6167a32e9cc4a-portilll]; Alvarez, Mayra (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=966dc355bf5a4efca30a542e28d8064a-alvarezlope]
Subject: RE: Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors Useful for Treating Cancer to Apexx Oncology. Notice for comment published in 83 FR 29562.

Mark,

Thanks. I will request my colleague, Mayra to send you the call in information for 3 .30PM today, if it still works for you.

Regards,

Sury

Phone: 301-827-7181
Cell: [REDACTED] b6
E-Mail: sury.vepa@nih.gov

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, July 10, 2018 4:57 PM
To: Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov>; Portilla, Lili (NIH/NCATS) [E] <portilll@mail.nih.gov>
Subject: RE: Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors Useful for Treating Cancer to Apexx Oncology. Notice for comment published in 83 FR 29562.

I have time until 5:30 today or tomorrow after 3. Does that work?

From: Vepa, Sury (NIH/NCATS) [E]
Sent: Tuesday, July 10, 2018 4:42 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Portilla, Lili (NIH/NCATS) [E] <portilll@mail.nih.gov>
Subject: Fwd: Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors Useful for Treating Cancer to Apexx Oncology. Notice for comment published in 83 FR 29562.

Mark and Lili, I would like to discuss with you on how to respond to another email from KEI (see below) asking for more detailed information. Please let me know your availability for a brief call. Mark, if you think we can do this by email, please advise. Thanks, Sury

Sent from my iPhone

Begin forwarded message:

From: James Love <james.love@keionline.org>
Date: July 10, 2018 at 4:35:07 PM EDT
To: "Vepa, Sury (NIH/NCATS) [E]" <sury.vepa@nih.gov>
Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>, Claire Cassedy <claire.cassedy@keionline.org>, Manon Ress <manon.ress@keionline.org>, Thiru Balasubramaniam <thiru@keionline.org>

REL0000024893.0001

Subject: Re: Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors Useful for Treating Cancer to Apexx Oncology. Notice for comment published in 83 FR 29562.

July 10, 2018

Sury Vepa, Ph.D., J.D.,
Senior Licensing and Patenting Manager,
National Center for Advancing Translational Sciences
National Institutes of Health
Email sury.vepa@nih.gov

Re: Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors Useful for Treating Cancer to Apexx Oncology. Notice for comment published in 83 FR 29562.

<https://www.federalregister.gov/documents/2018/06/25/2018-13486/prospective-grant-of-exclusive-patent-license-mutant-idh1-inhibitors-useful-for-treating-cancer>

Dear Dr. Vepa,

Knowledge Ecology International (KEI) offers the following comments on the, "Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors Useful for Treating Cancer," to Apexx Oncology, which was noticed in the Federal Register (83 FR 29562).

As far as the public can determine, Apexx Oncology is a secretive startup company. The only information we could find using a Google search about the company was a contest for a logo of the company. There is no record of a registered trademark for Apexx Oncology with the USPTO. No web page has been located. It is not obvious if Apexx Oncology is a new name for GeneXion Oncology (as indicated today), or a new company entirely, and in any case, there is next to nothing generally known about the company under either name.

When the NIH proposes giving an exclusive license on a patent to a company for which almost nothing is known, it should provide at the very least some basic information about the company. In seeking to respond to the first FR notice in this case, we had asked if GeneXion was owned by a company in Switzerland, but the NIH declined to answer. We don't know who is on the board of directors, who the key staff are or if another company owns this company. We would like to know if any current or former NIH employees or contractors are part of the company.

We also seek to learn -- why this company was selected in the first place? Do they have people who have worked on this particular technology, or have some special expertise? And since the patents are fairly new, did the NIH have no reasonable prospects for a license to an entity with more resources and a stronger track record than a company that seems to barely exist?

Here are some general provisions that we recommend for an exclusive license by the NIH.

1. No discrimination against US residents in pricing.

Prices in the U.S. for any drug, vaccine, medical device or other health technology using the invention should not be higher than the median price charged in the seven countries

with the largest gross domestic product (GDP), that also have a per capita income of at least 50 percent of the United States, as measured by the World Bank Atlas Method.

2. Developing countries.

The license should not be exclusive for countries with a per capita income that is less than 30 percent of the US.

3. Transparency.

The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product that uses the invention, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions.

4. Reduce term of exclusivity when revenues are large.

The exclusivity of the license in the U.S. should be reduced by one year for every \$500 million in revenue equivalents, earned after the first \$1 billion, where revenue equivalent is defined as global cumulative sales plus market entry rewards as well as government grants or tax credits, for the product or products using the invention.

Sincerely,



James Love
Knowledge Ecology International
james.love@keionline.org
<https://keionline.org>

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,

twitter.com/jamie_love

From: Mowatt, Michael (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB1EF7E2E54B4164AE34814574BDA638-MMOWATT]
Sent: 6/19/2018 6:42:24 PM
To: Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Frisbie, Suzanne (NIH/NIAID) [E] [suzanne.frisbie@nih.gov]; Sayyid, Fatima (NIH/NIAID) [E] [sayyidf@od.nih.gov]; Kirby, Tara (NIH/NIAID) [E] [tara.kirby@nih.gov]; Surabian, Karen (NIH/NIAID) [E] [karen.surabian@nih.gov]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Puglielli, Maryann (NIH/NIAID) [E] [maryann.puglielli@nih.gov]; Soukas, Peter (NIH/NIAID) [E] [peter.soukas@nih.gov]
CC: Thurston, Kelly (NIH/NIAID) [C] [kelly.thurston@nih.gov]; Williams, Richard (NIH/NIAID) [E] [rwilliams@niaid.nih.gov]
Subject: FW: KEI License
Attachments: FW: Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection
Location: 6C100
Start: 6/27/2018 5:00:00 PM
End: 6/27/2018 5:30:00 PM
Show Time As: Busy

Required Attendees: Mowatt, Michael (NIH/NIAID) [E]; Frisbie, Suzanne (NIH/NIAID) [E]; Sayyid, Fatima (NIH/NIAID) [E]; Kirby, Tara (NIH/NIAID) [E]; Surabian, Karen (NIH/NIAID) [E]; Rohrbaugh, Mark (NIH/OD) [E]; Puglielli, Maryann (NIH/NIAID) [E]; Soukas, Peter (NIH/NIAID) [E]
Optional Attendees: Thurston, Kelly (NIH/NIAID) [C]; Williams, Richard (NIH/NIAID) [E]

Hi Mark,

NIAID recently published the following Federal Register Notice for an Intent to Grant an Exclusive:

<https://www.federalregister.gov/documents/2018/06/15/2018-12838/prospective-grant-of-exclusive-patent-commercialization-license-streptococcus-pneumonia-psaa-peptide>

KEI responded with the attached. We were wondering if you would be willing to discuss a proposed response with us. Kelly Thurston, our new Admin. Assistant, has set up a meeting invite currently for June 27th. If this is not convenient, please let us know.

Thank you in advance for your advice!

Suzanne

-----Original Appointment-----

From: Mowatt, Michael (NIH/NIAID) [E]
Sent: Tuesday, June 19, 2018 2:28 PM
To: Mowatt, Michael (NIH/NIAID) [E]; Frisbie, Suzanne (NIH/NIAID) [E]; Sayyid, Fatima (NIH/NIAID) [E]; Kirby, Tara (NIH/NIAID) [E]; Surabian, Karen (NIH/NIAID) [E]; Rohrbaugh, Mark (NIH/OD) [E]
Subject: KEI License
When: Wednesday, June 27, 2018 1:00 PM-1:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: 6C100

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English (United States)
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.....

Request by Karen

From: Surabian, Karen (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=604A0E2013504631921434A90B327010-SURABIANK_1]
Sent: 6/18/2018 3:57:45 PM
To: Frisbie, Suzanne (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c402740ceaad4d4f97a8c28f16fbb349-frisbies]
CC: Kirby, Tara (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2368a591fa4c4932a802e5d467fb49ed-tarak]; Sayyid, Fatima (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b9e45041bdb43719f7113a5aae27057-sayyidf]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]
Subject: FW: Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection
Flag: Follow up

Karen T. Surabian
Licensing and Patenting Manager
CDC Team
Technology Transfer and Intellectual Property Office (TTIPO)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
5601 Fishers Lane, Rm. 2G48, MSC 9804
Rockville, MD 20892

Phone: [+1-301-594-9719](tel:+1-301-594-9719)
Email: karen.surabian@nih.gov

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From: James Love <james.love@keionline.org>
Sent: Monday, June 18, 2018 5:17 AM
To: Surabian, Karen (NIH/NIAID) [E] <karen.surabian@nih.gov>
Cc: Manon Ress <manon.ress@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>
Subject: Re: Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection

While we wait for answers to the questions asked, KEI can offer initial comments on the license.

1. We object to granting exclusive rights in any country with per capita income less than 30 percent of U.S per capita income, as measured by the World Bank Atlas method. We don't think the incentive provided by extending the license to the lower income countries is significant, and we think the negative impact on access is significant.

2. We suggest NIAID reserve an option to provide the Medicines Patent Pool rights to license to the invention to generic manufacturers in all countries with per capita income less than 30 percent of U.S. per capita income.
3. KEI suggests the initial period of exclusivity is set at seven years, subject to extensions if the company can demonstrate it has not recovered sufficient profits given the risk-adjusted value of the clinical trials used to register similar drugs for the lead indication. Absent a shorter license term, we propose the exclusivity of the product be reduced when cumulative global revenues for the product exceed \$1 billion, by one year for every \$0.5 billion in cumulative sales that exceed \$1 billion in cumulative sales. The NIH might consider a different set of benchmarks than \$1 billion and \$.5 billion. In considering any benchmarks for global sales benchmarks, note that the licensing of inventions to the company significantly reduces the company's costs of preclinical research, which various studies have estimated to be 40 to 55 percent of drug development costs on a risk- and capital cost-adjusted basis.
4. To prevent discrimination against US resident, products based upon the licensed patents should be priced no higher in the United States than the median price charged in the seven largest economies as measured by nominal GNI that have a nominal GNI per capita of at least 50 percent of the United States. To fully appreciate our concerns about the discriminatory pricing that makes US residents pay more than everyone else, please review the cross country price comparisons here: <http://drugdatabase.info/drug-prices/>
5. Prices for products in the United States should also not exceed the estimated value of the treatment, as determined by independent health technology assessments selected by Department of Health and Human Services (HHS).
6. To address transparency, we proposes the company be required to provide an annual report for the public providing disclosures of the following items:
 - a. The amount of money R&D to obtain FDA and foreign government approvals of the inventions, including in particular, the amount of money spent each year on each trial, and the relevant tax credits, grants and other subsidies received from any government or charity relating to those R&D outlays,
 - b. The prices and revenue for the products, by country,
 - c. The number of units sold, in each country,
 - d. The product-relevant patents obtained in each country, and
 - e. The regulatory approval obtained in each country.

On Mon, Jun 18, 2018 at 10:48 AM, James Love <james.love@keionline.org> wrote:

Karen Surabian,
Licensing and Patenting Manager,
Technology Transfer and Intellectual Property Office,
National Institute of Allergy and Infectious Diseases,
5601 Fishers Lane, Suite 6D, MSC9804, Rockville, MD 20852-9804,
phone number 301-496-2644
karen.surabian@nih.gov

RE:

Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection

Dear Karen Surabian,

I have a few questions about this license.

1. What is the proposed royalty and other consideration?
2. Has the NIAID undertake an economic analysis of term of the license that is necessary, given the limits on the scope of rights for exclusive license in 35 USC 209?
3. Will the invention be manufactured in the United States?
4. Where will the research and development be performed?
5. Are any former NIH employees involved in the license?
6. Has NIAID requested DOJ to revenue the license, under 40 USC 559?

James Love
Knowledge Ecology International

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, twitter.com/jamie_love

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, twitter.com/jamie_love

From: Rodriguez, Richard (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8092CB5394E04733AC0D4D84D25F65E5-RODRIGR]
Sent: 2/26/2018 4:09:05 PM
To: Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [berkleyd@od.nih.gov]

Subject: Discuss latest KEI Matter

Attachments: RE: NIH decision to proceed with the license of the anti-CD30 CAR tech to Kite/Gilead

Location: Call

Start: 2/26/2018 7:00:00 PM

End: 2/26/2018 7:30:00 PM

Show Time As: Busy

Required Attendees: Rohrbaugh, Mark (NIH/OD) [E]; Berkley, Dale (NIH/OD) [E]

The Main Number is: b6

The Conference Room ID Number is: b6

The PIN # is: b6

From: Andrew Goldman [andrew.goldman@keionline.org]
Sent: 2/14/2018 8:40:04 PM
To: Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]
CC: Jamie Love [james.love@keionline.org]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: NIH decision to proceed with the license of the anti-CD30 CAR tech to Kite/Gilead

Dear Dr. Lambertson:

In your email of Jan. 25, 2018 to Knowledge Ecology International, you stated NIH's intention to proceed with the license of anti-CD30 CAR technology to Kite Pharma/Gilead, as noticed in the Federal Register Vol. 82, No. 243, pp. 60406-7.

It is our understanding that under 37 CFR 404.11, there is a right of appeal of "any decision or determination concerning the grant, denial, modification, or termination of a license." Knowledge Ecology International timely filed its comments on this particular proposed license and qualifies for the right of appeal under subsection (a)(3) as a public interest organization representing patients and taxpayers that will be damaged by the agency action.

Please let us know what formal procedures the NIH requires for these appeals, as I did not see relevant guidelines or policies any on the NIH website. If there are none, we will follow up this email with a document detailing the arguments of our appeal.

As a side note, the link to chapter 307 of the HHS Technology Transfer Policies on NIH Procedures for Handling Requests for Reconsideration and Appeals of Licensing Decisions appears to be broken: <https://spweb.od.nih.gov/OTT/DTDT/TTPB/US%20PHS%20Technology%20Transfer%20Policy%20Manual/PHS%20TT%20Manual%20Chapters%20-%20Approved%20by%20TTPB/307-Procedure.pdf>

Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org

From: Mowatt, Michael (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB1EF7E2E54B4164AE34814574BDA638-MMOWATT]
Sent: 5/14/2019 10:50:14 AM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: Re: IP Watchdog blog about march-in and KEI

Thanks for sharing.

Michael R. Mowatt, Ph.D.
Director, Technology Transfer and Intellectual Property Office
National Institute of Allergy and Infectious Diseases
National Institutes of Health
U.S. Department of Health and Human Services
+1 301 496 2644

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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, May 13, 2019 5:20:55 PM
To: NIH TDC Long
Subject: IP Watchdog blog about march-in and KEI

<https://www.ipwatchdog.com/2019/05/12/knowledge-ecology-international-letter-misleads-march-rights/id=109152/>

Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer
Office of Science Policy
National Institutes of Health

From: Lambert, Richard (NIH/NIAID) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9668E9326D084AC893665B084FDFD4FE-LAMBERTR]
Sent: 5/13/2019 11:42:25 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: Re: IP Watchdog blog about march-in and KEI

Thanks Mark!

From: "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>
Date: Monday, May 13, 2019 at 5:21:01 PM
To: "NIH TDC Long" <niaaatdcl-l@mail.nih.gov>
Subject: IP Watchdog blog about march-in and KEI

<https://www.ipwatchdog.com/2019/05/12/knowledge-ecology-international-letter-misleads-march-rights/id=109152/>

Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer
Office of Science Policy
National Institutes of Health

From: Lampe, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3F3DDCC39C7E44ACA2125C44E5B51111-LAMPEKE]
Sent: 5/15/2020 10:41:28 AM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: KEI Covid-19 request
Attachments: 3202020 KEI FOIA Request NIDDK.pdf

I'm sorry Mark, I must have forgotten to attach it. I've attached it here.

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Thursday, May 14, 2020 2:36 PM
To: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Subject: RE: KEI Covid-19 request

I looked through it. [REDACTED] b5 would like to see the request letter. I did not see it attached to the email on in SEFT. Thanks

From: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Sent: Thursday, May 14, 2020 10:18 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: KEI Covid-19 request

Good morning Mark,

One of the open KEI cases that was sent to you is a request related to covid-19. It's been granted expedited processing

[REDACTED] b5
[REDACTED] b5 The records are two grant progress reports for a cystic fibrosis grant at UNC. They mention remdesivir in only a few places and thus are only tangentially related to covid-19. I don't think [REDACTED] b5

[REDACTED] b5
[REDACTED] b5 I'm going to send the files to you via SEFT because they're too large to send via regular email. If I recall correctly you mentioned that you'd never used SEFT. You will get an email with a link to click that will take you to SEFT. All NIH employees have an account that can receive emails but you will have to choose a password (make sure to remember it). Once you do that you can access the email and files. The files will be down at the bottom of the page and you can check the box next to each file and download them. If you have any problems or questions you can give me a call at

[REDACTED] b6

Thanks,

Karen E. R. Lampe, Ph.D.
Government Information Specialist
NIH Freedom of Information Office (HNA83)
karen.lampe@nih.gov



1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
www.keionline.org

March 20, 2020

Marianne Manheim
National Institute of Diabetes and Digestive and Kidney Diseases
Room 6054
6705 Rockledge Dr.
Bethesda, MD 20817
Email: nhlbfoiarequest@nhlbi.nih.gov
Via the Online Portal

Re: Freedom of Information Act Request Related to COVID-19 Pandemic with Request for Expedited Processing

Dear Ms. Manheim:

Under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, Knowledge Ecology International (KEI) requests all records related to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)'s role in the preclinical and clinical research on remdesivir (also referred to as GS-5734).

This request includes, but is not limited to, all records related to Project No. P30 DK065988 that mention "remdesivir" or "GS-5734".

Responsive records may include, but are not limited to, budget estimates, funding requests, awarded grant applications, PHS 398 and SF 424 forms, progress reports, PHS 2590 reports, grant reports, Research Performance Progress Reports (RPPRs), Federal Financial Reports (SF 425), expenditure reports, completed R&R and PHS 398 Modular Budget Forms.

The period of this request is from 2012 to present.

Request for Expedited Processing

The Department of Health and Human Services (HHS) grants expedited processing of FOIA requests when "failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual" or the

requesting party is an organization primarily engaged in the dissemination of information and “[t]here is an urgent need to inform the public about an actual or alleged Federal Government activity[.]” 45 C.F.R. § 5.27.

This request satisfies both aspects of the second basis for expedited processing.

1. KEI is an organization primarily engaged in the dissemination of information.

KEI’s Articles of Incorporation provide that education of the public and other constituencies is among KEI’s core purposes. Indeed, KEI’s very mission is inextricably linked with access to knowledge and information. Specifically, KEI’s Articles of Incorporation state that KEI:

is organized and will be operated exclusively for charitable, educational, and scientific purposes. Specifically, the Corporation will perform research, educate the public and other constituencies, and contribute to policy discourse and debate on issues relating to intellectual property, innovation, economics, international trade, consumer protection, law, and access to knowledge and the fruits of knowledge . . .

KEI disseminates information through its website, <https://keionline.org>, which hosts an extensive archive that is regularly consulted by advocates, academics, and the press.

For additional information about how KEI disseminates information concerning matters of public interest, please see Annex 1.

2. The information sought is urgently needed to inform the public about actual or alleged government activity.

Our request concerns actual government activity because it pertains to a federal agency’s role in conducting or funding biomedical research.

There is a strong public interest in ensuring that federally-funded technologies to address the COVID-19 pandemic are reasonably priced. Remdesivir is one of the leading candidates being investigated as a treatment for coronavirus and is the farthest along in the drug development process.¹ If remdesivir is not priced reasonably, health outcomes could suffer. The requested records will help clarify what it cost to develop remdesivir and how much of that expense was shouldered by the American public.

The records are urgently needed because this crisis is rapidly unfolding, and the rate of infection is increasing at an alarming pace. On March 17, 2020, Johns Hopkins reported that the number

¹ <https://www.statnews.com/2020/03/16/remdesivir-surges-ahead-against-coronavirus/>.

of coronavirus cases had doubled in a span of four days.² If and when a remdesivir treatment receives FDA approval, the U.S. government will want to ensure that it is distributed as quickly as possible. Gilead has said that it expects to produce data in April related to remdesivir's efficacy.³ If expedited processing is not granted, the responsive records may no longer be relevant by the time they become available.

Request for Full Waiver of Fees

KEI requests that the processing fee be waived pursuant to 5 U.S.C. § 552(a)(4)(A), which requires a responding agency to waive FOIA fees when disclosure "is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government," and "is not primarily in the commercial interest of the requester."

The subject of this request concerns the operations of the federal government because it pertains to a federal agency's role in sponsoring or conducting biomedical research and development.

The disclosures will likely contribute to public understanding of the role that the federal government played in the development of remdesivir. KEI has published or been quoted widely with respect to issues concerning government management of intellectual property as it relates to the public interest, consumer interest, and public health. James Love, Director of KEI, has personally written on these issues in publications such as *the Financial Times* and in several academic and policy journals.

The stories listed in Annex 1 demonstrate how KEI effectively uses FOIA requests to widely disseminate information that is in the public interest.

The request is not in KEI's commercial interest because KEI is a nonprofit, 501(c)(3) public interest organization. Granting this fee waiver request would fulfill Congress's legislative intent in amending the Freedom of Information Act. *See Judicial Watch, Inc. v. Rosetti*, 326 F.3d 1309, 1312 (D.C. Cir. 2003) ("Congress amended FOIA to ensure that it be liberally construed in favor of waivers for noncommercial requesters.") (quotation marks omitted).

Additional Comments

Please provide the documents requested in electronic format.

²

<https://myemail.constantcontact.com/COVID-19-Updates---March-17.html?soid=1107826135286&aid=UZamM7u0cpw>.

³

<https://endpts.com/a-japanese-flu-drug-gets-upbeat-reviews-in-china-after-small-trials-indicate-it-may-blunt-the-impact-of-covid-19/>.

We request the identification of any withheld records with specificity, including descriptions of the withheld material in detail, the specific statutory exemption or basis for denial, the reasons that the statutory exemption or denial applies in this instance, and the interests that would be foreseeably harmed by disclosure of the record. If this request is denied in whole or part, please justify all such denials by reference to specific exemptions, and provide an explanation of why the NIH "reasonably foresees that disclosure would harm an interest" protected by that exemption or why "disclosure is prohibited by law[.]" 5 U.S.C. § 552(a)(8).

Please also ensure that all segregable portions of otherwise exempt material are released.

We look forward to your determination regarding our request for expedited processing within 10 calendar days of receiving this request, as required by 5 U.S.C. § 552(a)(6)(E)(ii).

Please contact us if you have any questions about our request for records or if you require additional information in support of our request for a fee waiver. You may contact us by sending an email to kei-foia-request@keionline.org.

Thank you in advance for your assistance.

Pursuant to 5 U.S.C. § 552(a)(6)(E)(vi), I, James Packard Love, certify that the information described above as the basis for expedited processing of this request is true and correct to the best of my knowledge and belief.

Sincerely,

A handwritten signature in cursive script, appearing to read "James Packard Love".

James Packard Love
Director
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009
james.love@keionline.org

ANNEX 1

KEI is a not-for-profit non-governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. KEI has particular expertise on issues relating to intellectual property rights, technology transfer, the economics of innovation including the incentives to invest in biomedical research and development and the production of data, software and cultural works, policies regarding privacy, and more generally the production and management of and access to knowledge goods.

KEI has the ability and intention to effectively convey the information contained in the requested records to the public. KEI operates websites including keionline.org and drugdatabase.info that are used to disseminate information to the public, at no charge and without advertising, as well as several listservs, such as ip-health, which also has an open archive.

KEI is regularly consulted by advocates, academics, the press, legislators and officials working in governments and intergovernmental bodies. KEI seeks the requested records to provide fact-based and useful commentary on public policy issues. KEI uses social media as well as its own websites and listservs to directly distribute that analysis to the broad audience of persons interested in the subject of the request. KEI also publishes research and commentary in a variety of widely read news outlets, journals and blogs.

The following are examples of KEI's use of FOIA responses to inform the public, published at keionline.org.

- 2019 September 11. "FOIA: Records of USTR Lighthizer Bilateral Meetings at 2018 World Economic Forum in Davos";
- 2017 February 28. "CDC FOIA shows US, WHO opposed request to discuss UNSG's High-Level Panel on Access to Medicines Report at EB";
- 2016 October 18. "Kite Pharma Uses CRADAs to Conduct Important Clinical Research on New Cancer Treatments";
- 2016 September 19. "500+ Pages of Documents on NFL Attempts to Influence NIH Funding of Concussion Studies";
- 2016 September 16. "NIH Waivers for U.S. Manufacturing Requirements for Federally-Funded Drugs"; and
- 2017 June 8. "FOIA documents: In 2015 Novartis asked U.S. Dept of Commerce to Pressure Colombia Against Compulsory License on Glivec."

The following are examples of KEI's use of data from FOIA requests in the open source database drugdatabase.info:

- <http://drugdatabase.info/fda-orange-book-patents/>;
- <http://drugdatabase.info/nih-exclusive-licenses/>; and
- <http://drugdatabase.info/cradas/>.

Additionally, KEI works closely with journalists to provide analysis of documents obtained by KEI under the FOIA. KEI does not merely distribute documents to journalists, but provides in-depth analysis that later becomes the basis for stories. These are a few examples:

- 2017 March 3. Vidya Krishnan, "[U.S. nixed India's plea on reforms in medicine](#)," *The Hindu*;
- 2016 December 31. Dan Vergano, "If Taxpayers Invent A Drug, Should The Government Just Give It Away?," *Buzzfeed News*;
- 2016 December 19. Matt Richtel and Andrew Pollack, "PUBLIC LABS, CORPORATE GAINS: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits," *New York Times*. [Front page](#).
- 2013 June 22, Kimberly Kindy, "Filmmakers' group tries to reshape treaty that would benefit the blind," *the Washington Post*; and
- 2013 June 24. Paige McClanahan, "US film industry tries to weaken copyright treaty for blind people: Treaty to make copyrighted works available for visually impaired people – 90% of whom live in global south – coming up against film lobby," *The Guardian*.

Examples of articles written by KEI staff include the following:

- 2019 September 18. James Love, "Why didn't nonprofits and the NIH require 'reasonable' pricing for Zolgensma? That may happen in France," *STAT News*;
- 2019 April 2. "USMCA Agreement and the Remedies for Patent Infringement." *Bill of Health*, Petrie-Flom Center at Harvard Law School;
- 2019 May 21. Luis Gil Abinader and Jorge L. Contreras, "The Patentability of Genetic Therapies: CAR-T and Medical Treatment Exclusions Around The World," *American University International Law Review*;
- 2019 July 2. James Love and Ellen't Hoen, "Time to make essential cancer drugs more affordable: Governments can do more to pressure makers to bring down prices," *Financial Times*;
- 2018 September 24. Michael S. Sinha, Mehdi Najafzadeh, Elizabeth K. Rajasingh, James Love, Aaron S. Kesselheim, "Labeling Changes and Costs for Clinical Trials Performed Under the US Food and Drug Administration Pediatric Exclusivity Extension, 2007 to 2012," *JAMA Intern Med.* (doi:10.1001/jamainternmed.2018.3933);
- 2017 Oct 21. James Love, "Errors in Patent Grants: More Common in Medical Patents," *Bill of Health*, Petrie-Flom Center at Harvard Law School; and
- 2015 December 3. James Love and Andrew S. Goldman, "Colombia Asked To Declare Excessive Price For Cancer Drug Contrary To Public Interest, Grounds For Compulsory License," Inside Views, *IP-Watch.Org*.

From: Lampe, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3F3DDCC39C7E44ACA2125C44E5B51111-LAMPEKE]
Sent: 5/14/2020 2:24:12 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: KEI FOIA 53788 - Covid-19

Good morning Mark,
Attached are the request letter and two boxed grant progress reports responsive to the request. Please give them a quick look and let us know if you have any concerns about their release.

Thanks,
Karen

You have been sent a secure message/file(s).

To access the secure message/file(s), click on the following link or copy and paste the link into the browser.

Sender : Karen Lampe
Link : <https://secureemail.nih.gov/bds/Login.do?id=A06683762583&p1=naj26qbsbhhjeihdgjelcbfdeebbc30>

Sent To : Rohrbaugh, Mark (NIH/OD) [E]
Expires : 6/14/20, 12:00:00 AM EDT

NIH SecureEmail Service, brought to you by the NIH Central Email Service.
*Proven*Trusted*

From: Baxter, Merissa (NIH/NCI) [F] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=792B65733B4C468089E6D1563F8A9E34-BAXTERML]
Sent: 5/12/2020 7:40:23 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: McGuinness, Charlotte (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=920f87916f8441f387c5ab78e5081191-mcguinnnc]; Guyton, Nicole (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=044774e2efe14e749e7b8fcc3f43ae3f-guytonn]; Chang, Kevin (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a302166bdd0841caa4d1db06cec6e3a1-changke]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]
Subject: RE: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)
Attachments: DRAFT Response Letter_AevisBio.docx

Hello Mark,

Please find my proposed draft response to KEI attached. My supervisors (copied) have already reviewed it. Thank you for your input.

Best,
Merissa

Merissa Baxter, Ph.D.
Technology Transfer Manager
Technology Transfer Center
National Cancer Institute
National Institutes of Health

9609 Medical Center Drive
Rm 1E-406, MSC 9702
Rockville, MD 20850-9702
240-276-7234 | merissa.baxter@nih.gov

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Monday, May 11, 2020 10:56 AM
To: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Cc: McGuinness, Charlotte (NIH/NCI) [E] <mcguinnnc@mail.nih.gov>; Guyton, Nicole (NIH/NCI) [E] <darackn@mail.nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Subject: RE: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Merissa:

Your colleagues should have examples of responses. Here is a recent one:

b5

b5

Please

have your supervisors and me review the proposed draft.

REL0000024907

Thanks,
Mark

From: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>
Sent: Monday, May 11, 2020 10:13 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Cc: McGuinness, Charlotte (NIH/NCI) [E] <mcguinnnc@mail.nih.gov>; Guyton, Nicole (NIH/NCI) [E] <darackn@mail.nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Subject: FW: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Hi Mark and Richard,

I received this email from KEI at COB on Friday. I am forwarding it along to ask how best to proceed. I have not responded to KEI. Thank you.

Best Regards,
Merissa

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Friday, May 8, 2020 4:59 PM
To: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>
Cc: James Love <james.love@keionline.org>
Subject: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Dear Dr. Baxter:

Attached, please find the comments of Knowledge Ecology International regarding the "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743).

Thank you,

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

REL0000024907



DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health/ NCI
9609 Medical Center Drive, Suite 530
Rockville, MD 20852
Office (240) 276-5530
Facsimile (240) 276-5504

May 12, 2020

Kathryn Ardizzone, Esq.
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009
+1.202.332.2670
kathryn.ardizzone@keionline.org

Subject: KEI Comments "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Dear Ms. Ardizzone,

b5

Sincerely,

Merissa Baxter, Ph.D.
Technology Transfer Manager

From: Baxter, Merissa (NIH/NCI) [F] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=792B65733B4C468089E6D1563F8A9E34-BAXTERML]
Sent: 5/11/2020 2:13:16 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]
CC: McGuinness, Charlotte (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=920f87916f8441f387c5ab78e5081191-mcguinnnc]; Guyton, Nicole (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=044774e2efe14e749e7b8fcc3f43ae3f-guytonn]; Chang, Kevin (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a302166bdd0841caa4d1db06cec6e3a1-changke]
Subject: FW: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)
Attachments: KEI Comments, Prospective NIH Patent License to AevisBio.pdf

Hi Mark and Richard,

I received this email from KEI at COB on Friday. I am forwarding it along to ask how best to proceed. I have not responded to KEI. Thank you.

Best Regards,
Merissa

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Friday, May 8, 2020 4:59 PM
To: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>
Cc: James Love <james.love@keionline.org>
Subject: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Dear Dr. Baxter:

Attached, please find the comments of Knowledge Ecology International regarding the "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743).

Thank you,

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

REL0000024908



1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
www.keionline.org

May 8, 2020

Merissa Baxter, Ph.D.
Technology Transfer Manager
NCI Technology Transfer Center
Via Email to merissa.baxter@nih.gov

Re: “Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases” (85 FR 22743)

Dear Dr. Baxter:

Knowledge Ecology International (KEI) is writing to comment on the “Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases” to AegisBio, Inc (“AegisBio”).¹ We object to the National Institute of Health (NIH)’s lack of transparency regarding the license and apparent failure to fulfill its statutory obligations under 35 U.S.C. § 209 and 40 U.S.C. § 559.

The inventions covered by the license are “thalidomide/lenalidomide/pomalidomide (POMA) analogue compounds” to treat “neurological disorders prevalent in aging”—“Traumatic Brain Injury (TBI), Alzheimer’s disease (AD), Parkinson’s disease (PD), and Multiple Sclerosis (MS).”²

The prospective licensee, AegisBio, does not maintain a website. While the Federal Register notice lists its location as Gaithersburg, MD, AegisBio is not registered to conduct business in Maryland, according to Maryland’s online business records. According to his LinkedIn profile, the CEO of AegisBio is Dong Seok Kim.³ Kim’s profile states that he was a Research Scholar with the NIH from 2015 to 2017.⁴

¹ 85 Fed. Reg. 22743, available at <https://www.federalregister.gov/documents/2020/04/23/2020-08560/prospective-grant-of-an-exclusive-patent-license-thio-compounds-and-thalidomide-analogues-for-the-treatment-of-neurological-diseases>.

² *Id.*

³ <https://www.linkedin.com/in/dong-seok-kim-08a2a740/>.

⁴ *Id.*

We are concerned that the NIH is moving forward with this license without satisfying its obligations under the Bayh-Dole Act, 35 U.S.C. § 200 *et seq.*

The NIH may not execute the license unless it considers all timely-submitted public comments and concludes that the criteria listed at 35 U.S.C. § 209(a) are satisfied. These include that “granting the license is a reasonable and necessary incentive” to induce a company to commercialize the invention, and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]” 35 U.S.C. § 209(a)(1)-(2).

The NIH did not answer the majority of the questions KEI asked about the license, limiting our ability to comment on it. The questions the NIH declined to answer include how it evaluated whether “the license is a reasonable and necessary incentive” and how it determined that “the proposed scope of exclusivity . . . is not greater than reasonably necessary[.]” From what we can tell, however, the NIH has not engaged in an individualized assessment of these criteria.

Specifically, in refusing to answer KEI’s questions about the necessity and duration of exclusivity, Dr. Merissa Baxter—the point of contact for the license—referred KEI to a letter addressed to KEI by Dr. Mark Rohrbaugh in which he strongly implies that the NIH routinely grants exclusive rights to NIH patents for life of patent, because such terms are, in his view, always necessary to incentivize commercial development of the inventions. Yet Rohrbaugh himself has recognized, the value of inventions to investors depends on the circumstances.⁵ If the NIH has not considered whether a nonexclusive license or a term of exclusivity shorter than life of patent could provide the necessary incentive, the NIH has not fulfilled its obligations under the Bayh-Dole Act.

We do note, however, that the NIH has limited the scope of the license in one respect, because the proposed field of use does not embrace all potential commercial applications for the inventions. While the proposed field of use is limited to neurological disorders, the inventions could also be developed for applications in cancers and “[i]nflammatory disorders such as Crohn’s disease, sarcoidosis, graft-versus-host disease, and rheumatoid arthritis[.]”⁶ We appreciate the effort to limit one aspect of the scope of the license but the Bayh-Dole Act requires that all aspects of exclusivity, including the period of exclusivity, are limited to “not broader than the necessary incentive.”

We also object to the license unless the NIH first requests the antitrust advice of the U.S. Attorney General, which it is required to do under 40 U.S.C. § 559 because the license disposes of government-owned property.

⁵ Mark L. Rohrbaugh, *NIH: Moving Research from the Bench to the Bedside*, Testimony before the House Committee on Energy and Commerce, Subcommittee on Health, July 10, 2003, available at <https://www.govinfo.gov/content/pkg/CHRG-108hhrg88429/html/CHRG-108hhrg88429.htm>.

⁶ <https://www.ott.nih.gov/technology/e-208-2015>.

If the NIH grants the license, we request that it incorporates the following provisions designed to safeguard the public interest in the invention, promote the policy objectives of the Bayh-Dole Act, and implement the policies outlined in the Public Health Service (PHS) Technology Transfer Manual:

1. **Geographic Scope of Exclusivity.** If the NIH decides to grant exclusive rights to the subject inventions, it should limit exclusivity to any country with at least 35 percent of the per capita income of the United States, but not the United States, so that high income countries that did not fund the R&D underlying the invention would bear the costs of the exclusivity, while U.S. residents would not. The NIH should license the invention on a non-exclusive basis in countries with per capita incomes less than 35 percent of the United States. For countries of moderate or low income, the monopoly is likely to have an adverse impact on access with fewer benefits in terms of the incentives for investors.
2. **Price discrimination.** In the event that exclusivity is extended to the United States, any medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.
3. **Low and middle income countries.** As noted, the exclusive license should not extend to countries with a per capita income less than 35 percent of that of the United States, in order to ensure that the patents do not lead to restricted and unequal access. If the NIH rejects this suggestion, it needs to provide something that will give effect to the policy objective in the “United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy,” which states the following: “PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries.”
4. **Global registration and affordability.** The license should require AevisBio to disclose the steps it will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the WHO, either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.
5. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the medical technology from competitive suppliers, including technology transfer, in any

country where there is a finding by the Department of Health and Human Services (HHS) or the WHO that people in these markets do not have sufficient access to the medical technology.

6. **Years of exclusivity.** We propose the license reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddl case. We propose that the exclusivity of the license be reduced when the global cumulative sales from products or services using the invention exceed certain benchmarks. For example, the period of exclusivity in the license could be reduced by one year for every \$500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]”
7. **Transparency of R&D outlays.** AevisBio should be required to file an annual report to the NIH, available to the public, on the R&D costs associated with the development of any product or service that uses the invention, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward, the company be required to report on actual R&D outlays to develop the subject invention. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, including that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.” Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk-adjusted costs of bringing NIH-licensed inventions to practical application.

Conclusion

The NIH’s failure to answer KEI’s questions about this license has undermined our ability to comment on it. The NIH may not execute the license unless it fulfills all criteria listed at 35 U.S.C. § 209(a), and assumptions about industry preferences may not replace the necessary individualized assessment. Because the license disposes of government-owned property, the NIH may not grant the license unless it first requests the antitrust advice of the U.S. Attorney General. In the event that the NIH grants the license, we ask that it incorporates the provisions listed above, which are designed to protect the public interest in the licensed technologies and to accomplish the policies outlined in the PHS Technology Transfer Manual.

Sincerely,

Knowledge Ecology International

From: Baxter, Merissa (NIH/NCI) [F] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=792B65733B4C468089E6D1563F8A9E34-BAXTERML]
Sent: 5/11/2020 2:09:18 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Questions re: "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Hi Mark,

I trust you saw this email sent from KEI on Thursday? I have made my supervisors aware of the email in a separate email, so they are not copied here. I will be forwarding you another email shortly. This email was sent at COB on Friday (the FRN deadline). In light of the email below and the email I will soon forward, I wanted to ask how best to proceed.

Best,
Merissa

From: Kathryn Ardizzone <kathrynardizzonekei@gmail.com>
Sent: Thursday, May 7, 2020 5:32 PM
To: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: James Love <james.love@keionline.org>
Subject: Re: Questions re: "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Dr. Baxter:

The questions I asked are relevant and neither you, nor anyone at NIH, has answered them.

Dr. Rohrbaugh, did you direct Dr. Baxter and other licensing officers not to answer our questions?

I joined KEI less than a year ago. In the short time I've been with the organization, I've encountered several statements from you that indicate a disdain toward our efforts to ensure that NIH patent licenses are lawful and serve the public interest. It is hard to fathom why a public servant, entrusted with the role of overseeing NIH technology transfer, would maintain such a dismissive attitude toward a representative of the public interest.

As you made clear from your letter, NIH gives away the broadest possible rights to cell and gene therapies, regardless of the circumstances, because it assumes that such terms are always necessary to incentivize commercial development. We have a different perspective. We believe the NIH's one-size-fits-all approach is inconsistent with the Bayh-Dole Act and a dereliction of the NIH's duty to consider the facts of each case. Our comments demonstrate what a proper, fact-specific analysis might look like.

We can disagree about the facts, and how they apply to the law, but it cannot be disputed that the Bayh Dole Act gave the public a voice in licenses to federally-owned inventions. **You are treating that voice as irrelevant.**

Assuming that you don't lack respect for the public's right to comment and its role in funding NIH patents and that this is merely a communication gap, I would like to work with you to resolve this impasse. Please let me know when we can schedule a zoom call to address these issues.

Sincerely,

Kathryn Ardizzone

REL0000024909

On Wed, May 6, 2020 at 2:57 PM Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov> wrote:

Hello,

Both of the technologies are in the pre-clinical stage of development. The answers to your remaining questions are either irrelevant to the criteria for granting an exclusive license, or have been previously addressed. Please refer to the letter provided to KEI from Mark Rohrbaugh dated November 26, 2019.

Best Regards,

Merissa

Merissa Baxter, Ph.D.

Technology Transfer Manager

Technology Transfer Center

National Cancer Institute

National Institutes of Health

9609 Medical Center Drive

Rm 1E-406, MSC 9702

Rockville, MD 20850-9702

240-276-7234 | merissa.baxter@nih.gov

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Tuesday, May 5, 2020 10:24 AM

To: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>

Cc: James Love <james.love@keionline.org>

Subject: Questions re: "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Dear Dr. Baxter:

REL0000024909

At your earliest convenience, but prior to the close of the comment period on Friday, please answer the following questions regarding the "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743).

1. At what stage of research and development are the two inventions covered by the proposed license?
2. Are the inventions being investigated in any clinical trials? If so, can you please provide their numbers?
3. Please estimate how much the NIH has spent to develop the inventions (or, if that is not possible, list any NIH intramural grants associated with the inventions).
4. **On what basis did the NIH conclude that an exclusive license was a necessary incentive under 35 U.S.C. § 209(a)(1)?**
 - a. Did you perform any analysis of other incentives such as Orphan Drug exclusivity, pediatric rare disease priority review vouchers, test data exclusivity, etc.?
 - b. Did you estimate the cost of bringing the technologies to market?
5. How many years will the license be exclusive?
6. **How has the NIH determined that the scope of the license is not broader than necessary?**
7. Did you seek the antitrust advice of the U.S. Attorney General regarding the license?
8. Please provide a list of the firms that applied to license the inventions.

Thank you in advance for your assistance.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

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REL0000024909

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From: Mowatt, Michael (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB1EF7E2E54B4164AE34814574BDA638-MMOWATT]
Sent: 5/8/2020 3:00:23 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: STAT: The U.S. government contributed research to a Gilead remdesivir patent — but didn't get credit <https://bit.ly/2WAI2bO>

In case you've not already seen this

From: Ganelina, Anna (NIH/NIAID) [E] <anna.ganelina@nih.gov>
Sent: Friday, May 8, 2020 9:58 AM
To: NIAID TTIPO <OTD@niaid.nih.gov>
Subject: FW: STAT: The U.S. government contributed research to a Gilead remdesivir patent — but didn't get credit <https://bit.ly/2WAI2bO>

From: Folkers, Greg (NIH/NIAID) [E] <gfolkers@niaid.nih.gov>
Sent: Friday, May 8, 2020 9:11 AM
Subject: STAT: The U.S. government contributed research to a Gilead remdesivir patent — but didn't get credit <https://bit.ly/2WAI2bO>

The U.S. government contributed research to a Gilead remdesivir patent — but didn't get credit

By [ED SILVERMAN](#) @Pharmalot
MAY 8, 2020



JOSH EDELSON/AFP VIA GETTY IMAGES

Two documents dating back to 2015 shed further light on the role the federal government played in discovering remdesivir and its use in treating coronaviruses — work that has taken on new meaning

as the Gilead Sciences (GILD) drug has gained global attention and an emergency use authorization from federal regulators to treat patients with Covid-19.

....

The role played by the federal government in developing remdesivir to combat coronaviruses has, in fact, involved various grants to universities, as well as contributions from government personnel at such agencies as the U.S. Army Medical Research Institute of Infectious Diseases, according to Knowledge Ecology International, an advocacy group that first disclosed these connections.

But while it remains unclear the extent to which federal funds contributed to the R&D, the patent is of particular interest because it is tangible evidence that government work yielded something of potential financial value to the company. Yet government employees are not listed as inventors, which one expert suggested should be corrected, especially in an era when federally financed research might be leveraged to collect royalties or, arguably, lower the price of medicines.

More

<https://bit.ly/2WAl2bO>

From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 5/8/2020 2:24:39 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: Questions re: "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)
Location: b6
Start: 5/8/2020 5:00:00 PM
End: 5/8/2020 5:30:00 PM
Show Time As: Tentative

Required Attendees: Rohrbaugh, Mark (NIH/OD) [E]

Yes, 1pm sounds good. Give me a call at b6 if you would.

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Friday, May 8, 2020 10:13 AM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: RE: Questions re: "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

1?

From: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Sent: Friday, May 8, 2020 9:05 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: RE: Questions re: "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Sure. Maybe later this morning or after lunch?

Dale D. Berkley, Ph.D., J.D.
NIH Branch
Office of The General Counsel
9000 Rockville Pike
Building 31, 2B-47
Office: 301-496-6043
Email: berkleyd@nih.gov

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Thursday, May 7, 2020 5:51 PM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: FW: Questions re: "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Should we talk about this?

From: Kathryn Ardizzone <kathrynardizzonekei@gmail.com>

Sent: Thursday, May 7, 2020 5:32 PM

To: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>

Cc: James Love <james.love@keionline.org>

Subject: Re: Questions re: "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

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Sincerely,

Kathryn Ardizzone

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Hello,

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Best Regards,

Merissa

Merissa Baxter, Ph.D.

REL0000024911

Technology Transfer Manager

Technology Transfer Center

National Cancer Institute

National Institutes of Health

9609 Medical Center Drive

Rm 1E-406, MSC 9702

Rockville, MD 20850-9702

240-276-7234 | merissa.baxter@nih.gov

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Tuesday, May 5, 2020 10:24 AM

To: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>

Cc: James Love <james.love@keionline.org>

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Thank you in advance for your assistance.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

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Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

From: Lampe, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3F3DDCC39C7E44ACA2125C44E5B51111-LAMPEKE]
Sent: 5/7/2020 3:19:04 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: KEI request 45669

Good morning Mark.

Gorka has looked at the files and wishes to know if

b5

b5

b5

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Wednesday, May 6, 2020 1:44 PM
To: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Subject: RE: KEI request 45669

yes

From: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Sent: Wednesday, May 6, 2020 2:44 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: RE: KEI request 45669

I figured that's what you meant. Just to be sure,

b5

b5

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Wednesday, May 6, 2020 12:51 PM
To: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Subject: FW: KEI request 45669

I meant

b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, May 6, 2020 1:41 PM
To: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Subject: FW: KEI request 45669

Thanks Karen.

b4,b5

b5

b4,b5

From: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Sent: Wednesday, May 6, 2020 11:07 AM

REL0000024914

To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>

Subject: KEI request 45669

Good morning Mark,

Attached are royalty distribution forms responsive to request 45669 (also attached). They've been boxed as OTT has redacted them in the past. Please review b5 before we apply the redactions and release to KEI.

Thanks,

Karen E. R. Lampe, Ph.D.

Government Information Specialist

NIH Freedom of Information Office (HNA83)

karen.lampe@nih.gov

From: Garcia-Malene, Gorka (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C4DA0F5E0A0480AAD2A86924CABA7B7-GARCIAMALEN]
Sent: 5/6/2020 7:16:54 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Lampe, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f3ddcc39c7e44aca2125c44e5b51111-lampeke]
Subject: RE: NIH FOIA 46229 KEI - Adapt-Emergent BioSolutions - NIH FOIA Intent to Release
Attachments: NIH FOIA Case 46229 KEI - Adapt-Emergent BioSolutions - NIH FOIA Intent to Release

Hi Mark,

It looks like these were sent to you, if that helps. Please see the attached for that reference.

Let me know if there are any questions.

Gorka

From: Garcia-Malene, Gorka (NIH/OD) [E]
Sent: Wednesday, May 6, 2020 3:01 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Subject: RE: NIH FOIA 46229 KEI - Adapt-Emergent BioSolutions - NIH FOIA Intent to Release

Hi Mark,

I don't know [REDACTED] b5

I think we could send you the collection so you can peruse it. If you're familiar with SEFT, I could send it that way.

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Wednesday, May 6, 2020 1:14 PM
To: Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>
Cc: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Subject: RE: NIH FOIA 46229 KEI - Adapt-Emergent BioSolutions - NIH FOIA Intent to Release

Thanks Gorka. [REDACTED] b5
[REDACTED] b5 If it is easier to send me examples, that would be fine.

From: Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>
Sent: Wednesday, May 6, 2020 1:08 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Subject: NIH FOIA 46229 KEI - Adapt-Emergent BioSolutions - NIH FOIA Intent to Release

Good afternoon, Mark –

We are working on processing the attached FOIA request from KEI. It involves records from Adapt-Emergent BioSolutions. We have spent the last 7 months, off and on, providing them with opportunities to comment on our proposed redactions, to no avail. At this point, we are planning on releasing the records with our redactions. Before I

REL0000024915

do so, I wanted to loop you in on the request. I'm happy to send you the responsive records, though note that they total over 1,000 pages.

Let me know if there are any questions.

Gorka

From: Bordine, Roger (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A44282B444584690BBBE471966F54F1F-BORDINERW]
Sent: 4/9/2020 4:39:45 PM
To: FoxJ@ebsi.com; woubished@ebsi.com
CC: NIH FOIA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e734b867d58f45e792d9fa7096aa146d-nihfoia]
Subject: NIH FOIA Case 46229 KEI - Adapt-Emergent BioSolutions - NIH FOIA Intent to Release
Attachments: 46229 KEI - Adapt-Emergent BioSolutions - NIH FOIA Intent to Release.pdf

Good Afternoon,

Please see the attached letter from the NIH FOIA office concerning a request for records regarding your company. We are sending you the related records noted in the letter via the NIH Secure Email File Transfer (SEFT) system that you can register and access here: <https://secureemail.nih.gov>

Please let us know if you have any questions.

Thank you.

Roger Bordine
Program Support
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov



National Institutes of Health
Turning Discovery Into Health

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

April 9, 2020

Jennifer Fox
VP, Associate General Counsel, IP
Emergent BioSolutions Inc.
FoxJ@ebsi.com

&

Daniel Woubishet
Assistant General Counsel
Legal Department
Emergent BioSolutions Inc.
woubished@ebsi.com

400 Professional Drive, Suite 400
Gaithersburg, MD 20879

RE: NIH FOIA Case No. 46229

Jennifer Fox and Daniel Woubishet:

This is in reference to an National Institutes of Health Freedom of Information Act request (NIH FOIA) addressed to the National Institute on Drug Abuse (NIDA) under NIH FOIA case number 46229, submitted by Knowledge Ecology International (KEI). NIH received request 46229, seeking 1,175 pages of your records.

Since July 8, 2019, the NIH has attempted to contact your company on multiple occasions to verify whether your company has any concerns regarding the release of said records. We have yet to receive any response. Consequently, **please be advised that we intend to release the records in question with our proposed redactions (attached) on May 1, 2020.**

Release of the responsive records is controlled by Federal law, specifically the federal Freedom of Information Act, 5, U.S.C. §552. The FOIA mandates that records in the possession or control of the federal government must be released upon request unless one or more of the FOIA's nine exemptions or three exclusions applies.

REL0000024915.0001.0001

Therefore, in accordance with Department of Health and Human Services FOIA Regulations, 45 C.F.R. § 5.65(d)(3), the records originating from your company that the NIH possesses will be released as expunged no later than noon, May 1, 2020. The NIH has redacted portions of information from these records pursuant to Exemption 4 of the FOIA, 5 U.S.C. §552(b)(4).

Sincerely,

Gorka Garcia-
malene -S

Digitally signed by Gorka
Garcia-malene -S
Date: 2020.04.09 10:14:34
-04'00'

Gorka Garcia-Malene
FOIA Officer, National Institutes of Health

Enclosure: PDF containing 1,175 pages

From: Baxter, Merissa (NIH/NCI) [F] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=792B65733B4C468089E6D1563F8A9E34-BAXTERML]
Sent: 5/6/2020 3:17:09 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]; McGuinness, Charlotte (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=920f87916f8441f387c5ab78e5081191-mcguinnnc]
CC: Guyton, Nicole (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=044774e2efe14e749e7b8fcc3f43ae3f-guytonn]; Chang, Kevin (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a302166bdd0841caa4d1db06cec6e3a1-changke]
Subject: RE: Questions re: "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Hello Everyone,

Please find my draft responses to KEI in red. Let me know if you have any suggested changes. Mark, would you prefer that I copy you when I respond to KEI? Thank you all for your assistance.

1. At what stage of research and development are the two inventions covered by the proposed license? **b5**
b5

2. Are the inventions being investigated in any clinical trials? If so, can you please provide their numbers? **b5**
b5

3. Please estimate how much the NIH has spent to develop the inventions (or, if that is not possible, list any NIH intramural grants associated with the inventions). **b5**
b5

4. On what basis did the NIH conclude that an exclusive license was a necessary incentive under 35 U.S.C. § 209(a)(1)? **b5**
b5

a. Did you perform any analysis of other incentives such as Orphan Drug exclusivity, pediatric rare disease priority review vouchers, test data exclusivity, etc.? **b5**
b5

b. Did you estimate the cost of bringing the technologies to market? **b5**
b5

5. How many years will the license be exclusive? **b5**
b5

6. How has the NIH determined that the scope of the license is not broader than necessary? **b5**
b5

7. Did you seek the antitrust advice of the U.S. Attorney General regarding the license? **b5**
b5

8. Please provide a list of the firms that applied to license the inventions. **b5**

b5

Best,
Merissa

From: Baxter, Merissa (NIH/NCI) [F]
Sent: Tuesday, May 5, 2020 5:15 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Cc: Guyton, Nicole (NIH/NCI) [E] <darackn@mail.nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>; McGuinness, Charlotte (NIH/NCI) [E] <m McGuinnnc@mail.nih.gov>
Subject: RE: Questions re: "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Thank you, Mark and Richard. I'll draft a response for your review.

Merissa

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Tuesday, May 5, 2020 5:10 PM
To: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>
Cc: Guyton, Nicole (NIH/NCI) [E] <darackn@mail.nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>; McGuinness, Charlotte (NIH/NCI) [E] <m McGuinnnc@mail.nih.gov>
Subject: RE: Questions re: "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

See my corrected suggested response

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, May 5, 2020 5:05 PM
To: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>
Cc: Guyton, Nicole (NIH/NCI) [E] <darackn@mail.nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>; McGuinness, Charlotte (NIH/NCI) [E] <m McGuinnnc@mail.nih.gov>
Subject: RE: Questions re: "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Merissa:

You may

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Please run the draft response by your NCI colleagues and me. Thanks,

Mark

From: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Sent: Tuesday, May 5, 2020 3:27 PM
To: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>
Cc: Guyton, Nicole (NIH/NCI) [E] <darackn@mail.nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>;

REL0000024918

McGuinness, Charlotte (NIH/NCI) [E] <mcguinncc@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>

Subject: RE: Questions re: "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Hi Merissa,

Responses to KEI all go through Mark Rohrbaugh. I'm copying him on this response.

Mark, this is Merissa's first exclusive license and objection from KEI so any assistance you can provide would be much appreciated. I've provided some general guidance below and also provided comments where we should not respond given previous KEI responses.

Thanks,

Richard

From: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>

Sent: Tuesday, May 5, 2020 3:03 PM

To: McGuinness, Charlotte (NIH/NCI) [E] <mcguinncc@mail.nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>

Cc: Guyton, Nicole (NIH/NCI) [E] <darackn@mail.nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>

Subject: FW: Questions re: "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Hi Richard and Charlotte,

I recently received the email below from counsel at Knowledge Ecology International (<https://www.keionline.org/about>) regarding my recently published notice to grant an exclusive license (links below) to Aegisbio. I would like your guidance on how to best address the list of question. If you think it best to discuss via conference call, please let me know your availability and I'll send a calendar invite. Please note, I'll need to respond before the deadline on Friday, May, 8, 2020. Thank you.

Main site

<https://www.federalregister.gov/documents/2020/04/23/2020-08560/prospective-grant-of-an-exclusive-patent-license-thio-compounds-and-thalidomide-analogues-for-the>

PDF

<https://www.govinfo.gov/content/pkg/FR-2020-04-23/pdf/2020-08560.pdf>

Merissa

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Tuesday, May 5, 2020 10:24 AM

To: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>

Cc: James Love <james.love@keionline.org>

Subject: Questions re: "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Dear Dr. Baxter:

At your earliest convenience, but prior to the close of the comment period on Friday, please answer the following questions regarding the "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743).

1. At what stage of research and development are the two inventions covered by the proposed license? **b5**

2. Are the inventions being investigated in any clinical trials? If so, can you please provide their numbers? **b5**

3. Please estimate how much the NIH has spent to develop the inventions (or, if that is not possible, list any NIH intramural grants associated with the inventions). **b5**

b5

4. On what basis did the NIH conclude that an exclusive license was a necessary incentive under 35 U.S.C. § 209(a)(1)? **b5**

a. Did you perform any analysis of other incentives such as Orphan Drug exclusivity, pediatric rare disease priority review vouchers, test data exclusivity, etc.? **b5**

b. Did you estimate the cost of bringing the technologies to market? **b5**

5. How many years will the license be exclusive? **b5**

6. How has the NIH determined that the scope of the license is not broader than necessary? **b5**

b5

7. Did you seek the antitrust advice of the U.S. Attorney General regarding the license? **b5**

b5

8. Please provide a list of the firms that applied to license the inventions. **b5**

b5

Thank you in advance for your assistance.

Sincerely,

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From: Wilson, Artisha (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9CE4AF5515C44E18A8754F8AABE11B7A-WILSONARR]
Sent: 5/6/2020 3:14:16 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Garcia-Malene, Gorka (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4da0f5e0a0480aad2a86924caba7b7-garciamalen]
Subject: NIH FOIA 51097- Proposed Review
Attachments: Responsive Records - Proposed Redactions.pdf

Good morning, Mark,

My name is Artisha Wilson, I'm a member of the OD FOIA team with Karen Lampe under the direction of Gorka Garcia Malene.

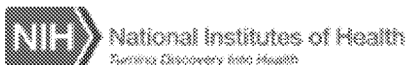
I'm reviewing FOIA request 51097 from KEI. The responsive record contains a copy of Kite Pharm's *draft* Patent License Agreement Application. NCI alerted Kite Pharma of this request and returned with proposed redactions. NCI in turn agreed to those proposed redactions. When you have a moment, I wonder whether you might peruse Kite Pharm's proposed redactions before they are sent to KEI. Otherwise, simply let us know that you don't see the need to review the record, which is attached.

If you have any question, please feel free to contact me at any time.

Thank you,

Artisha Wilson
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541



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From: Portilla, Lili (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9B03F548BE224EB9B7B6167A32E9CC4A-PORTILL] [E]
Sent: 9/18/2019 2:02:48 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: NIH News Briefing for Wednesday, September 18, 2019
Attachments: NIHNewsBriefing190918.doc

From: Temple-O'Connor, Meredith (NIH/NCATS) [E]
Sent: Wednesday, September 18, 2019 8:25 AM
To: Austin, Christopher (NIH/NCATS) [E] <austinc@mail.nih.gov>; Rutter, Joni (NIH/NCATS) [E] <joni.rutter@nih.gov>; Burgoon, Penny (NIH/NCATS) [E] <penny.burgoon@nih.gov>; Portilla, Lili (NIH/NCATS) [E] <portilll@mail.nih.gov>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>
Subject: FW: NIH News Briefing for Wednesday, September 18, 2019

<https://www.statnews.com/2019/09/18/zolgensma-reasonable-pricing-france/>

‘Reasonable’ Pricing Could Limit The Cost For Zolgensma In France.

In an opinion piece for STAT (9/18, Love, 24K) , James Love, director of Knowledge Ecology International and a board member of the of the Union for Affordable Cancer Treatment, writes that after the FDA approved Zolgensma in May, Novartis “set the price at \$2.1 million” because it can “charge whatever it wants for this therapy.” While NIH Director Francis Collins “has decided to leave pricing decisions to drug companies, without any limits,” things may be different in France. Généthon, a French nonprofit research center that “holds several key patents that were licensed to AveXis, a company created to commercialize Zolgensma,” included a “reasonable pricing clause,” according to an unredacted copy of the license. Love says this inclusion raises the question why US charities also “don’t insist on reasonable pricing agreements to protect access to the medicines they help make.”

Meredith D. Temple-O'Connor, Ph.D.

Director of Science Policy
Office of Policy, Communications, and Education (OPCE)
National Center for Advancing Translational Sciences (NCATS)
National Institutes of Health (NIH)/DHHS
templeocm@nih.gov

From: Bulletin Intelligence <HHS@BulletinIntelligence.com>
Sent: Wednesday, September 18, 2019 7:28 AM
To: Hall, Bill (HHS/ASPA) <Bill.Hall@HHS.GOV>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: NIH News Briefing for Wednesday, September 18, 2019

Click to access online version optimized for different mobile platforms, audio version, and fully searchable archives of NIH News Briefings.

TO: THE DIRECTOR AND SENIOR STAFF

DATE: WEDNESDAY, SEPTEMBER 18, 2019 7:30 AM EDT

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- UPMC To Receive State Grant To Study Ewing Sarcoma.
- Bethesda Man Will Box For Children's Cancer Funding.
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- Data Show Opioid-Related Deaths Declined In Maryland For Second Straight Quarter.
- HHS Awards \$2M Grant To Atlantic County Sheriff's Office For Opioid Training.
- Afghanistan, Iraq War Veterans Hit Hardest By Opioid Crisis, Study Finds.
- Athena Health Care Systems Will Now Accept Patients With Opioid Addictions.
- Report Reveals Number Of Abortions In US Declines To Lowest Rate Since 1973.
- Researchers Discover Possible Method To Cure Common Cold.
- Michigan Records Three Deaths Due To EEE.
- Rhode Island Confirms Two More Cases Of EEE.
- Minnesota Department Of Health Says 11 Infected With E. Coli After Visiting State Fair.
- Florida Surgeon General Warns Hepatitis A Epidemic Will Not End Anytime Soon.

- Pediatric Death In California May Indicate Worse Flu Season Than Usual In US.
- Study Suggests Women Over 75 With Chronic Illnesses Can Skip Screening Mammograms.
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- Study Suggests Harmful Airborne Carbon Particles Can Reach Placenta In Pregnant Women.
- Medical Experts Urging Use Of Precision Medicine To Identify Genetic Causes Of Disease, Tailor Therapies.
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- Rural Maine Hospital Files For Bankruptcy Protection.
- Hospitals' Means To Collect Unpaid Bills Highlighted.
- Vaccine Protesters In California Co-Opting Civil Rights Mantle.
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- AARP Wages Multimillion-dollar Campaign Against Pharmaceutical Industry.

Global Health News

- South Korea Confirms Second Case Of African Swine Fever At Pig Farm Near North Korea Border.
- Explosion Reported At Russian Laboratory That Holds One Of The World's Two Live Samples Of Smallpox.
- North Macedonia Turning To Growth Of Medicinal Marijuana For Economic Boost.
- France To Offer Free Iodine Tablets To People Living Near Nuclear Plants.
- While Childhood Mortality Has Fallen Overall, Some Places Still Have High Rates.

HHS in the News

- New York Becomes First State To Ban Sale Of Flavored E-Cigarettes.
- Seventh Person Dies From Lung Illness Tied To Vaping.
- Azar Met With Ugandan Minister Of Health.
- Azar Asks Tanzania For Transparency On Case Of Woman Who Died From Unknown Illness.
- Azar Led Delegation To Ebola Treatment Center In DRC.
- Some Brokers Selling Poor Insurance Policies Under ACA Exemptions.
- Tennessee Proposes Block Grant Reform For Medicaid.
- FDA Hosts Public Hearing To Discuss Standards For Future Opioid Analgesic Approvals.
- Roche's Obinutuzumab Receives FDA Breakthrough Therapy Designation For Lupus Nephritis.
- Hospitals Challenge HHS Regulation That Reduces Funding For Hospitals Training Medical Fellows.
- Federal Judge Tosses Out CMS Action On Hospital Outpatient Payments.
- Columnist Argues Right-To-Try Erodes Authority Of FDA And Undermines Public Health.

National Front Page News

- Headlines From Today's Front Pages.

Last Laughs

- Late Night Political Humor.

National News

- Trump: California Cities "Destroying Themselves" With Homelessness.

- Fed Intervenes To Keep Rates From Rising Above Target For First Time Since 2008.
- Manufacturing Production Rebounds.
- Senators Urge Antitrust Regulators To Strenuously Investigate Big Tech.
- Trump Says US, Japan Have Reached A Trade Deal.
- Proposed Rules Would Give Greater Scrutiny To Foreign Investment In US Tech, Infrastructure, Data.
- McConnell: Senate In "Holding Pattern" On Guns Until Trump Expresses Preferences.
- Teens Arrested For Three High School Shooting Plots In California, Oklahoma.
- Some Of Trump's Hurricane Briefings Do Not Include Meteorologists.
- Tropical Storm Imelda Forms, Posing Risk Of Flash Floods In Texas, Louisiana.
- Hurricane Humberto Gaining Strength.
- DeVos Visits Nontraditional School In Cleveland.
- Trump Names Five Finalists For National Security Adviser Post.
- Senate Panel To Vote On Scalia Nomination September 24.
- White House Fires DHS General Counsel.
- Administration Proposes New Rules To Streamline Disciplinary Process For Federal Employees.
- Media Analyses: Lewandowski Testimony Enrages Democrats.
- NYTimes Decries Democrats' Conflicting Messages On Impeachment.
- DOJ IG's Findings Are Driving Force Behind Possible Criminal Charges For McCabe.
- Comey Says He Is "Highly Confident" He Won't Be Indicted.
- Schiff: Acting DNI Has Refused To Hand Over Whistleblower Complaint.
- Blasey Ford Friend Says She Doubts Her Accusation Against Kavanaugh.
- Gorsuch Says He Opposes "Nine Older People Sitting In Washington Making Stuff Up."
- New York Judge Steps Down After Posting Trump Slogan With An Image Of A Noose.
- Sinema Faces Arizona "Censure" For Voting To Confirm Trump Nominees.
- Cook To Leave Congress, Plans To Run For County Supervisor.
- DOJ Lawsuit Seeks All Proceeds From Snowden's Memoir.
- Conservative Groups Urge Administration To Weaken Standards For Home Appliances.
- Army Experiments With New Recruiting Tactics.
- Car Crashes Into Lobby Of Trump Tower In New Rochelle.
- Veteran Journalist Cokie Roberts Dies.
- RNC Raised "Record-Setting" \$23.5M In August.
- Trump Camp Severs Ties With Key Florida Adviser At DeSantis' Urging.
- Businessman In North Macedonia "Hijacked" Facebook Page "Vets For Trump."
- WSJournal: GOP Leaders Shouldn't Cancel Presidential Primaries.
- NBC/WSJournal Poll: Biden 31%; Warren 25%; Sanders 14%; Buttigieg 7%; Harris 5%.
- Trump Camp Out With Video Targeting Biden On Gaffes.
- Trump Downplays Size Of Warren's NYC Crowd.
- Politico Analysis: Top Sanders Allies Worry He's Being Eclipsed By Warren.
- Carter Says He Doesn't Think He Could Handle Duties Of Presidency At 80.
- Ocasio-Cortez Endorses Liberal Newman's Primary Challenge To Lipinski.

- NYTimes Analysis: Some “Experts” Say Redrawn NC Political Maps Still Favor Republicans.
- WSJournal: Murkowski’s Move To Protect Alaska’s Salmon Industry Hurts Consumers.

NIH News

‘Reasonable’ Pricing Could Limit The Cost For Zolgensma In France.

In an opinion piece for [STAT](#) (9/18, Love, 24K) , James Love, director of Knowledge Ecology International and a board member of the of the Union for Affordable Cancer Treatment, writes that after the FDA approved Zolgensma in May, Novartis “set the price at \$2.1 million” because it can “charge whatever it wants for this therapy.” While NIH Director Francis Collins “has decided to leave pricing decisions to drug companies, without any limits,” things may be different in France. Généthon, a French nonprofit research center that “holds several key patents that were licensed to AveXis, a company created to commercialize Zolgensma,” included a “reasonable pricing clause,” according to an unredacted copy of the license. Love says this inclusion raises the question why US charities also “don’t insist on reasonable pricing agreements to protect access to the medicines they help make.”

What’s The Right Way To Reverse The Obesity Epidemic?

In an opinion for the [New York Times](#) (9/17, 18.61M), Spencer Bokart-Lindell discusses the “right way to reverse the obesity epidemic” in the wake of controversial “fat-shaming” comments by Bill Maher. Bokart-Lindell says, “The worldwide obesity rate has nearly tripled since 1975, according to the World Health Organization, but the problem is particularly acute in the United States: 39.8 percent of adults were obese in 2016, compared with only 15 percent in the late 1970s, according to the federal Centers for Disease Control and Prevention, the highest rate of any developed country.” NIH senior researcher Kevin Hall, PhD, attributes the continued exposure of Americans to food of poor nutritional quality to what he call the “push hypothesis.” Bokart Lindell concludes, “No doubt the problem requires many solutions, but all of them will have to match the scale and force of its reality.”

NINR Reopens Search For Director After Nurse Backlash.

[Becker’s Hospital Review](#) (9/17, Masson, 81K) reports that the National Institute of Nursing Research (NINR) on Monday reopened its search for a director after facing backlash over its appointment of dentist Lawrence Tabak, DDS, PhD, as interim director. The appointment, which “was met with immense backlash from nurses, who said NINR should be run by a nurse,” was the result of “a national search earlier this year failed to identify a suitable candidate, according to NIH.”

Nano-Sized Solution For Efficient And Versatile CRISPR Gene Editing.

[Science Blog](#) (9/17) reports that researchers supported by NIH have developed an alternative delivery system – nanocapsules – for CRISPR gene-editing technology, which “holds tremendous promise for treating or curing a wide range of devastating disorders, including sickle cell disease, vision loss, and muscular dystrophy.”

According to the [study](#) from a team that “is part of a nationwide consortium on genome editing supported by NIH’s recently launched Somatic Cell Genome Editing program,” nanocapsules “appear to pose a lower risk of side effects” and “can be precisely customized to deliver their gene-editing payloads to many different types of cells or tissues in the body, which can be extremely tough to do with a virus.”

'Social Jet Lag' May Contribute To Girls' Weight.

MedPage Today (9/17, Lyles, 75K) reports on a study led by "Elizabeth Feliciano, ScD, ScM, of Kaiser Permanente Northern California in Oakland," which found that the "sleep patterns and bedtimes" of teenage girls "were associated with risk of obesity." The study, which was funded by the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, and the National Institute of Diabetes and Digestive and Kidney Diseases, found that for female subjects, "each hour of 'social jet lag' – difference between weekdays and weekends in sleep midpoint, measured by actigraphy – was linked with 0.45 kg/m² greater fat mass index as assessed by dual-energy x-ray absorptiometry and a 1.19-cm larger waist circumference (P for interaction 0.01 and 0.21, respectively)." The study authors wrote, "This study suggests that female adolescents may be more vulnerable to the obesogenic effects of circadian misalignment; obesity prevention efforts should consider regular sleep-wake patterns in addition to sleep extension and sleep quality improvement."

UPMC To Receive State Grant To Study Ewing Sarcoma.

The Pittsburgh Post-Gazette (9/17, Templeton, 616K) reports that state legislators Rep. Jason Ortitay (R-South Fayette) and Rep. Tim O'Neal, (R-South Strabane) recently announced a \$100,000 state grant they landed that will enable hospital UPMC in Pittsburgh to carry out genetic research on patients with Ewing sarcoma as well as on their family members. In the next week, Rep. O'Neal "said, the State House is scheduled to vote on Resolution 483, which he authored, 'which urges Congress to direct the National Institutes of Health to conduct a comprehensive study on the causes of Ewing sarcoma.'"

Bethesda Man Will Box For Children's Cancer Funding.

Bethesda (MD) Magazine (9/17, McDonald) reports that Mike Dendas has raised nearly \$20,000 for The Children's Inn at NIH with a boxing match raised organized by national nonprofit Haymakers for Hope. Denda said that the Inn, a residential facility for children with serious illnesses and their families, was a "saving grace" during the time that his teenage cousin, Lizzie Schwanfelder, was battling clear cell carcinoma. Dendas said, "We had Yale right in our backyard and she could not get any of the treatments or they couldn't figure it out." However, Dendas said that The Children's Inn in Bethesda "had way more expertise with the type of disease my cousin was dealing with."

Wistar Wins \$4.6M NIH Grant For Studying For Studying Antibiotic Resistance.

The Philadelphia Business Journal (9/17, George, Subscription Publication, 860K) reports that the National Institutes of Health has awarded the Wistar Institute In University City a \$4.6 million four-year grant to support antibiotic research being conducted by "a team of researchers led by David B. Weiner, Wistar executive vice president and director of the its vaccine and immunotherapy center." The team "is looking to advance a nontraditional approach to combat multidrug resistance by bacteria that is based on a synthetic DNA technology called DNA-encoded monoclonal antibodies."

UAB CFAR Researchers Awarded Contracts To Aid The Ending The HIV Epidemic Plan.

The University of Alabama at Birmingham News (9/17, Koplon) reports that the National Institutes of Health awarded researchers from the University of Alabama at Birmingham (UAB) Center for AIDS Research (CFAR) three one-year supplemental awards totaling \$300,000 “to help develop plans for diagnosing, treating and preventing HIV in local communities, many of which are areas with high rates of new cases.” The grants will enable Latesha Eloppe, MD, and Lynn Matthews, MD, to “help carry out the Ending the HIV Epidemic agenda set by the Trump administration to diagnose, treat and prevent HIV.”

Cornell Medical School To Offer Full Scholarships For Students Who Qualify For Financial Aid.

USA Today (9/17, Miller, 10.31M) reports the Weill Cornell medical school announced it would offer full-ride scholarships “for its students who qualify for financial aid.” The school said in a statement that the program would begin this academic year and then continue “every year thereafter in perpetuity.” Furthermore, students pursuing dual degrees as part of a separate “joint MD-PhD program will receive full tuition and stipends for living expenses from the National Institutes of Health and Weill Cornell Medicine.”

Additional Source. Medscape (9/17, Brooks, Subscription Publication, 277K) reports that “first-year students in Weill Cornell Medicine’s class of 2023, who entered this fall, and those in every subsequent entering class will have their student loans replaced by scholarships for their entire education.” Meanwhile, “returning students who are eligible for financial aid and who matriculated prior to this year will receive scholarships that will replace their loans for this year and their remaining years as Weill Cornell Medicine medical students, the school said.” The article says that there Weill Cornell “joins a growing number of medical schools offering free tuition.”

Intermountain Offers Grants To Advance Genomics, Precision Medicine.

Health IT Analytics (9/17, Kent) reports that Intermountain Precision Genomics is offering up to \$200,000 in grants for biomedical research projects. The grants “will provide an opportunity for scientific collaboration and offer funding toward Intermountain Precision Genomics research services, including next-generation sequencing, sample procurement, bioinformatic analysis, and other processes.” Applications for the Genomic Innovation Grants “will be reviewed by a panel of scientists from different biomedical disciplines, and projects will be evaluated on the likelihood of providing scientific impact and influence on research based on NIH review criteria.”

Health & Medical News

Purdue Settlement Would Raise Money Through Further Opioid Sales.

The AP (9/17, Mulvihill, Galofaro) reports Purdue Pharma’s “tentative multibillion-dollar settlement” agreement “would raise money to help clean up the opioid mess by ... selling more OxyContin,” which “would amount to blood money, in the opinion of some critics,” and is “one reason two dozen states have rejected the deal.” The article says Purdue “filed for bankruptcy Sunday in the first step toward putting the settlement into effect.” The deal, which is “valued by Purdue at potentially more than \$10 billion over time,” would see the Sackler family, which owns Purdue, “give up ownership of the company,” which “would be reconstituted as a ‘public benefit trust.’ Its profits from opioids, as well as from overdose antidotes and addiction-treatment drugs, would go toward the settlement.”

Georgia Health Officials Say Purdue Settlement Funds Should Go Toward Opioid Recovery.

The Atlanta Journal-Constitution (9/17, Hart, 895K) continues coverage of Georgia Attorney General Chris Carr's announcement Monday that the state will accept Purdue Pharma's settlement agreement. According to the article, "Carr says the risk of fighting the deal is worse than taking what's offered and moving on." In a statement, Carr's office said, "The resources that will become available under the proposed structural framework will help Georgia combat the opioid crisis and address the needs of people living in our communities who have been devastated by the actions of those who fueled it." Likewise, "health officials said Tuesday that it's critical that the money go to substance abuse treatment and coping with the crisis." State Rep. Sharon Cooper, R-Marietta, Chairwoman of the House Health and Human Services Committee, said any money should be "used for recovery programs across our state," with "tight oversight to make sure that that's done."

South Carolina Attorney General Wilson Joins Settlement With Purdue. The Charlotte (NC)

Observer (9/17, Wilks, 470K) reports, "South Carolina Attorney General Alan Wilson has joined 23 states in agreeing to a proposed, multibillion-dollar settlement with" Purdue Pharma. On Tuesday, "Wilson's office confirmed...that South Carolina was among the 24 states and five U.S. territories that have signed onto the settlement." In a statement, Wilson said the company's bankruptcy, which was announced Sunday, "was expected and is part of a settlement framework which will put one of the worst actors responsible for the opioid epidemic in our country out of business, not only in the United States, but worldwide. It will take every penny from Purdue Pharma assets and billions from the Sackler family personally."

Holdout States Vow To Challenge Purdue Pharma Settlement. The Hill (9/17, Weixel, 2.98M)

reports states that have not signed on to Purdue Pharma's settlement "are gearing up for a fight in bankruptcy court and are expected to try to pursue Purdue's owners, the Sackler family, for a full accounting." In rejecting the deal, the states "criticized the settlement, saying that it is not nearly enough to address the opioid crisis and that it will take years before the full terms are realized, if at all."

Kasich, Gee: Hospitals Must Not Be Left Out Of Opioid Settlement. In an op-ed for the New York

Times (9/17, Kasich, Lee, 18.61M), John Kasich, former Governor of Ohio, and E. Gordon Gee, President of West Virginia University and Chairman of the West Virginia University Health System, who are both founders of Citizens for Effective Opioid Treatment, write that the opioid crisis has imposed a "staggering" cost on hospitals, "which provide billions of dollars of unreimbursed care." Looking back to the 1998 tobacco settlement, they point out that "hospitals and front line providers" were left out. The authors hope we will "learn the lessons of the tobacco settlement and use opioid settlement funds to help those who have been at the tip of the spear in fighting the epidemic and are most needed to deal with its aftermath in the years ahead."

WPost: Proposed Purdue Pharma Settlement Does Not Serve Justice. The Washington Post

(9/17, 14.2M) editorializes that plaintiffs seeking claims against Purdue Pharma are not only looking for money, but also "justice" and "accountability." However, "Purdue's proposal, which includes no new admission of wrongdoing, and which could be funded in large part from the proceeds of spinning off a Purdue international subsidiary, as well as future OxyContin sales, does not necessarily deliver that." The Post commiserates with those who are refusing to settle, and recognizes "why they would not want to settle before understanding the full nature and purpose of the \$1 billion that members of the Sackler family shuffled among trusts and overseas bank accounts, via wire transfer, in recent years."

Purdue To Stay In Business As Bankruptcy And Sackler Investigation Unfold.

The AP (9/17, Sisak) reports US Bankruptcy Judge Robert Drain on Tuesday “cleared the way” for “Purdue Pharma to stay in business while it pursues bankruptcy protection and settlement of more than 2,600 lawsuits filed against it in a reckoning over the opioid crisis.” The article says Purdue’s “continued viability” constitutes “a key component of the company’s settlement offer, which could be worth up to \$12 billion over time.”

Bloomberg (9/17, Church, Hill, 4.73M) explains, “One consequence of the bankruptcy is that Purdue and its board of directors is now responsible for pursuing any so-called fraudulent transfers the company made over the years to the Sackler family.” That could interfere “with any state or local officials who have either sued the Sacklers, or plan to sue them in order to recover the costs of dealing with the public health care crisis brought on by addictive painkillers. Under the U.S. Bankruptcy Code, lawsuits that could benefit creditors are considered the property of the bankrupt company.”

CNN (9/18, Ly, Vitagliano, 83.16M) also covers the story.

North Carolina Files Opioid Lawsuit Against Sackler Family.

The Hill (9/17, Weixel, 2.98M) reports North Carolina Attorney General Josh Stein filed a lawsuit against eight members of the Sackler family for allegedly “deliberately ignoring the harms of OxyContin [oxycodone] in order to boost the prescription painkiller’s sales as well as profits for themselves.” The lawsuit claims the family members were “the driving forces behind Purdue Pharma and its work to deceptively market and sell OxyContin.”

Data Show Opioid-Related Deaths Declined In Maryland For Second Straight Quarter.

The Washington Post (9/17, Wiggins, 14.2M) reports preliminary data released by Maryland officials on Tuesday show that fatal opioid-related overdoses in the state have declined for the second quarter in a row, marking “the first six-month drop in the last decade.” Specifically, “there were 1,060 opioid-related deaths in Maryland in the first half of the year, 133 fewer...than in the first six months of 2018,” which represents an 11 percent decline. Even so, “opioid-related deaths remain at nearly an all-time high in Maryland,” and “the state plans to spend \$747 million in fiscal year 2020 on opioid-related programs, up from \$674 million this fiscal year. State spending on opioid-related programs has jumped by nearly 68 percent in the past three years.”

HHS Awards \$2M Grant To Atlantic County Sheriff’s Office For Opioid Training.

The Press of Atlantic City (NJ) (9/17, Fairfield, 177K) reports, “The Atlantic County Sheriff’s Office has partnered with the Rowan University School of Osteopathic Medicine after receiving a four-year, \$2 million federal grant” from HHS’ Substance Abuse and Mental Health Services Administration “to provide overdose prevention training for first responders.” The sheriff’s office will use the grant to train personnel throughout the county, “distribute the opioid overdose reversal drug naloxone and train overdose survivors and their families on its use.” It will also use a portion of the money “to create an Atlantic County Quick Response Team that will work with the Hope One Mobile Recovery Unit operated by the Sheriff’s Office,” and to “enable the development of a curriculum to train first responders and community members on fentanyl safety.”

Afghanistan, Iraq War Veterans Hit Hardest By Opioid Crisis, Study Finds.

The Washington Examiner (9/17, Morrison, 448K) reports, "Veterans who were stationed in Afghan and Iraqi war zones after the 9/11 terror attacks have been hit hardest by the opioid crisis, according to new research" distributed by the National Bureau of Economic Research. Researchers found these veterans "have an opioid abuse rate about seven times higher than civilians who have never served in a combat zone." According to the article, researchers also "found that veterans not only deal with chronic pain that has to be treated when they return from war zones, but also post-traumatic stress that sometimes leads to drug use as a coping mechanism. ... The study's authors say that veterans didn't even have to be in the line of fire everyday to show an increased risk of opiate abuse and post-traumatic stress."

Athena Health Care Systems Will Now Accept Patients With Opioid Addictions.

The Boston Globe (9/17, Freyer, 972K) reports Athena Health Care Systems, in a settlement reached Tuesday with the office of US Attorney Andrew E. Lelling, "agreed to accept patients being treated for opioid addiction, forgoing a practice that remains common among other nursing homes." Under the terms of the deal, the health system "agreed to adopt a nondiscrimination policy, provide training to admissions personnel about the rights of disabled people and opioid addiction, and pay a civil penalty of \$10,000."

Report Reveals Number Of Abortions In US Declines To Lowest Rate Since 1973.

The Washington Post (9/18, Cha, 14.2M) reports, "A new Guttmacher Institute report released on Wednesday outlines dramatic changes in the abortion landscape between 2011 and 2017," and found "the U.S. abortion rate hit an all-time low – again." The report "provides detailed information by state and region about how American women access abortion." The Post adds, "The report estimated the abortion rate in 2017...at 13.5 per 1,000 women ages 15 to 44," compared to "14.6 in 2014 and 16.9 in 2011 and is the lowest rate since the U.S. Supreme Court legalized abortion through...Roe v. Wade in 1973." The report found a total of "862,320 abortions took place in 2017 at health-care facilities," and nearly "339,640, or about 39 percent, of those were medical abortions, which involve taking pills to induce miscarriage as opposed to traditional surgical abortion."


According to the New York Times (9/18, Belluck, 18.61M), the new report "suggests that one reason for the decrease might be the growing use of long-term contraceptive methods, like intrauterine devices and implants." Additionally, researchers "tried to assess the phenomenon of women ordering abortion medications on their own, without seeking it from clinicians in the United States, as is currently required by the Food and Drug Administration, "and "found that 18 percent of nonhospital facilities reported that they had treated at least one patient for a failed attempt at a 'self-managed abortion.'"

The Los Angeles Times (9/17, Haberkorn, 4.64M) reports that the decline "comes amid a declining pregnancy rate, greater access to contraception and a significant increase in restrictions on abortion in conservative-led states."

The AP (9/18, Cray) reports, "Federal data compiled by the Centers for Disease Control and Prevention excludes California, Maryland and New Hampshire."

The Hill (9/18, Hellmann, 2.98M) also covers the report.

Researchers Discover Possible Method To Cure Common Cold.

 ABC World News Tonight (9/17, story 11, 0:18, Muir, 6.62M) reported that “researchers at Stanford University and UCSF” made “a discovery they hope leads to a cure for the common cold.” The researchers “say disabling a single enzyme in cells may stop the virus from penetrating the cell and then spreading through the body,” and add that additional research is needed.

Michigan Records Three Deaths Due To EEE.

The Detroit Free Press (9/17, Shamus, 1.52M) reports three individuals in Michigan have died from Eastern equine encephalitis “and four others have been sickened by the disease, state health officials said Tuesday, amid the biggest outbreak in more than a decade.” Residents in “all eight of the affected counties – Kalamazoo, Cass, Van Buren, Berrien, Barry, St. Joseph, Genesee and Lapeer counties – are urged to consider canceling, postponing or rescheduling outdoor events that occur at or after dusk, especially those that involve children, according to the Michigan Department of Health and Human Services.”

Rhode Island Confirms Two More Cases Of EEE.

The AP (9/17) reports, “Rhode Island officials have confirmed two more human cases of eastern equine encephalitis this season.” The state’s “health and environmental management departments said Tuesday two people have been discharged from the hospital and are recovering, bringing the number of human cases of the virus to three.” Department officials “say a child younger than 10 years old from Coventry and an adult over 50 from Charlestown contracted the mosquito-borne disease, likely in late August.”

Minnesota Department Of Health Says 11 Infected With E. Coli After Visiting State Fair.

The AP (9/17) reports Minnesota Department of Health officials “say at least 11 people got sick with E. coli infections after visiting the Minnesota State Fair this summer” most likely due to contact with livestock at the Miracle of Birth exhibit. The article adds, “Six of the ill people were hospitalized, and one developed a potentially fatal complication.”

The Minneapolis Star Tribune (9/16, Olson, 1.04M) also reports.

Florida Surgeon General Warns Hepatitis A Epidemic Will Not End Anytime Soon.

The Miami Herald (9/17, Koh, 1.09M) reports, “Florida’s ongoing hepatitis A epidemic has already far eclipsed state records, but people shouldn’t expect the outbreak to end anytime soon, the state’s surgeon general says.” Scott Rivkees, who was recently “installed head of the state’s Department of Health, told lawmakers Tuesday that 3,009 cases of the virus have been reported this year as of September 7, and that the state is still working to vaccinate hundreds of thousands of high-risk or medically vulnerable patients to curb the virus’ spread.” The article adds that over “200,000 people have been vaccinated this year – a huge jump from the 49,324 people vaccinated in all of 2018 – but it is unclear what fraction of those vaccinated are part of the high-risk population that federal officials recommend should be 80% vaccinated to curtail an outbreak.”

Pediatric Death In California May Indicate Worse Flu Season Than Usual In US.

NBC News (9/17, Edwards, 6.14M) reports that Dr. Cameron Kaiser, a public health officer for Riverside County, California, announced the death of a 4-year-old with underlying problems in the state due to the flu. Kaiser said,

"A death so early in the flu season suggests this year may be worse than usual." NBC News features the opinions of various medical professionals who explain why getting the flu vaccine is so important.

Study Suggests Women Over 75 With Chronic Illnesses Can Skip Screening Mammograms.

The Chicago Tribune (9/17, Gordon, 2.65M) reports new research suggests women over 75 with chronic illnesses, like heart disease or diabetes, can probably skip regular screening mammograms as they "would likely die from those conditions before developing breast cancer." Study author Dejana Braithwaite said, "For those 75 and over with chronic illness, the benefit of continued mammography is minimal. Women 75 to 84 are 123 times more likely to die of other causes than breast cancer." However, Braithwaite continued, "It's important to individualize the decision. Women should discuss with their providers the potential benefits of continuing mammography."

Aerobic Exercise May Prevent Or Slow Cognitive Decline In People At High Risk For Alzheimer's Disease, Study Indicates.

CNN (9/17, Lamotte, 83.16M) reports researchers found that "a half hour of aerobic exercise four to five times a week may prevent or slow cognitive decline in older adults who are at a high risk of developing Alzheimer's" disease. The findings were published in the Journal of Alzheimer's Disease.

Study Suggests Harmful Airborne Carbon Particles Can Reach Placenta In Pregnant Women.

Reuters (9/17, Emery) reports, "Airborne carbon particles that can cause health problems in adults and children are getting into the placenta as it nourishes a developing fetus, a new study has found." The study included "tissue samples from 5 pre-term and 23 full-term births" and "found that the more airborne soot the mother was exposed to during pregnancy, the higher the number of so-called black carbon particles found in the placenta, researchers report." Researchers did not conclude whether or not these particles, "created by the combustion of fossil fuels, pose a direct risk to the fetus," but they "speculate that the pollutants may play a role in the low birth weight or premature delivery more often seen in babies whose mothers are exposed to higher levels of contaminated air."

The AP (9/17, Neergaard) reports, "The Belgian researchers developed a way to scan placenta samples using ultra-short pulses from a laser that made the black carbon particles flash a bright white light, so they could be measured." The "scanning technique spotted a type of particle pollution – sootlike black carbon – on placentas donated by 28 new mothers, they reported" in the study, published in Nature Communications.

Newsweek (9/17, Gander, 1.53M) reports the mothers in the study "were categorised as living in a highly polluted area if their home was located 500 meters (1,640 feet) or less from a major road, and exposed to an average yearly concentration of 2.42 micrograms per meter cubed of fine particulate matter during the year of their pregnancy." The article adds, "Tests revealed the women who lived in the highly polluted areas had more black carbon particles in their placentas," yet researchers "found black carbon in all of the placentas."

The Hill (9/17, Gstalter, 2.98M) and CNN (9/18, Yeung, 83.16M) also cover the study.

Medical Experts Urging Use Of Precision Medicine To Identify Genetic Causes Of Disease, Tailor Therapies.

The Washington Times (9/17, Tan, 492K) reports, "Medical experts and researchers are urging for the use of precision medicine to help identify genetic causes of disease and to tailor therapies for individual patients." In doing so, "physicians could pinpoint the biomarkers of a disease in a patient and apply treatments that work best based on that person's genetic profile, instead of relying on a traditional 'one-size-fits-all' approach, researchers said Tuesday in panel discussion." The use of precision medicine has already "been applied in cancer diagnosis and treatment."

Fluoroquinolone Antibiotics May Increase The Risk Of Heart Valve Problems, Study Indicates.

The New York Times (9/17, Bakalar, 18.61M) reports, "The class of antibiotics called fluoroquinolones (Cipro, Levaquin and others) may increase the risk of heart valve problems," researchers concluded after examining "antibiotic use among 12,502 people with heart valve regurgitation," then comparing "them with 125,020 healthy controls." The findings were published in the Journal of the American College of Cardiology.

North Carolina Children's Hospital To Resume Performing Complex Heart Surgeries.

The New York Times (9/17, Gabler, 18.61M) reports North Carolina Children's Hospital "that stopped performing complex heart surgeries in recent months after high death rates were disclosed may now resume the procedures, according to an advisory board that was examining the hospital's practices." The advisory board "noted 'significant investment and progress' had been made at" the hospital "while suggesting areas for improvement, including increasing the number of surgeries performed, a factor associated with better outcomes." The report released by the board "was one of several initiatives launched by UNC Health Care in response to a New York Times investigation in May that detailed turmoil at the medical institution in 2016 and 2017."

Rural Maine Hospital Files For Bankruptcy Protection.

The Bangor (ME) Daily News (9/17, Sambides Jr., 198K) reports Calais Regional Hospital in Maine "filed for Chapter 11 bankruptcy protection on Tuesday, but hospital officials promised that the 25-bed facility would stay open as the bankruptcy case proceeds." The Regional Hospital "blamed the bankruptcy filing in U.S. Bankruptcy Court in Bangor on a number of factors, including a drop in paying and insured patients; increased levels of care the hospital has had to provide for free; inadequate reimbursement from MaineCare, the state's Medicaid program; and increasing regulatory requirements." The filing "comes 11 days after the hospital's nursing staff voted to put the option of a strike on the table in contract negotiations that have dragged on for almost a year," and is the "second rural Maine hospital to file for bankruptcy protection this year."

Hospitals' Means To Collect Unpaid Bills Highlighted.

CBS News (9/17, Cerullo, 3.68M) reports, "Some hospitals are using increasingly aggressive means to collect on unpaid bills, including garnishing patients' wages and forcing them to sell their homes." The article highlights the University of Virginia Health System, which "filed roughly 36,000 lawsuits against patients over six years" and the "Carlsbad Medical Center in New Mexico," which "has sued more than 3,000 patients over 10 years." The article says hospitals across additional states "have employed the same tough tactics."

Vaccine Protesters In California Co-Opting Civil Rights Mantle.

Politico (9/18, Mays, 4.29M) reports that protesters in California who are opposed to childhood vaccine mandates have “co-opted the civil rights mantle from the 1960s, insisting that their plight is comparable to what African Americans have suffered from segregationist policies.” This month, hundreds of vaccine protesters throughout the state have galvanized “against legislation that would crack down on medical exemptions to childhood immunizations.”

Group Of Senators Urge FTC To Scrutinize Pharma Industry Mergers.

Reuters (9/17, Sibi Joseph) reports Sen. Amy Klobuchar (D-MN) on Tuesday “led a letter by U.S. senators that urged the Federal Trade Commission (FTC) to closely scrutinize pharma mergers, raising concerns about the potential harm to customers.” The deals “proposed by AbbVie and Bristol-Myers raise significant antitrust issues, the senators wrote, calling on the FTC to ‘take appropriate action’ to protect consumers from mergers that may threaten competition, raise drug prices or reduce patient access to essential medications.” Ed Silverman in his “Pharmalot” column for STAT (9/17, Silverman, 24K) reports the lawmakers “noted there has been a ‘steady increase’ in mergers and acquisitions in the pharmaceutical industry and also pointed to multibillion-dollar deals announced earlier this year by Pfizer (PFE) and Roche (RHHBY).”

AARP Wages Multimillion-dollar Campaign Against Pharmaceutical Industry.

STAT (9/17, Florko, 24K) highlights AARP’s “multimillion-dollar campaign against the pharmaceutical industry and its high prices.” AARP Senior Vice President of Campaigns John Hishta described the Stop Rx Greed campaign as “an all-hands-on-deck effort to raise the profile of the issue and to encourage action.” AARP Executive Vice President and Chief Advocacy and Engagement Officer Nancy LeaMond said of the campaign, “We saw alignment in four key areas: families in great need, policymakers on both sides looking for solutions, a workable legislative calendar, and an out-of-touch industry that can’t even admit there’s a problem.”

Global Health News

South Korea Confirms Second Case Of African Swine Fever At Pig Farm Near North Korea Border.

Reuters (9/17, Chung) reports South Korea “confirmed a second case of African swine fever at a pig farm near the border with North Korea, a day after reporting its first-ever outbreak of the virus.” South Korea’s “Ministry of Agriculture, Food and Rural Affairs said in a statement on Wednesday that the second case was detected at a farm in Yeoncheon, northwest of the capital Seoul, where 4,700 pigs had been raised.” Furthermore, the ministry said all pigs on the farm would be slaughtered.

Explosion Reported At Russian Laboratory That Holds One Of The World’s Two Live Samples Of Smallpox.

USA Today (9/17, Yancey-Bragg, 10.31M) reports that on Monday there was an explosion at the Russian State Centre for Research on Virology, “one of two places in the world that holds live samples of the smallpox virus.” The article says that “a gas cylinder exploded on the fifth floor of a six story laboratory building at the” facility causing a fire.

CNN (9/17, Regan, 83.16M) reports the lab said in a statement that there was no biohazardous material being stored in the room where the explosion happened.

North Macedonia Turning To Growth Of Medicinal Marijuana For Economic Boost.

Reuters (9/17, Sekularac) reports North Macedonia “legalised the growth of cannabis for medicinal purposes in 2016, joining a growing number of countries to have done so or be about to do so, such as Britain, Greece, Thailand and some U.S. states.” Since 2017, the country “has issued 28 licences for growth and production of cannabis oil and another 15 companies are waiting for permits,” yet “very little has been produced and no exports have been made as producers hone their skills.”

France To Offer Free Iodine Tablets To People Living Near Nuclear Plants.


Reuters (9/17, De Clercq) reports, “France will offer free iodine tablets to around 2.2 million people living close to nuclear plants to help protect them from radiation in case of an accident.” ASN, the country’s nuclear regulator, “said on Tuesday people living within 10-20 km of one of utility EDF’s 19 nuclear plants, as well as some 200,000 institutions such as schools, will receive a letter in coming days informing them that they can pick up free iodine tablets from pharmacies.”

While Childhood Mortality Has Fallen Overall, Some Places Still Have High Rates.

Josh Katz, Alicia Parlapiano, and Margot Sanger-Katz write in “The Upshot” blog for the New York Times (9/17, 18.61M) that childhood mortality has been “nearly cut in half” over the past two decades, “but the results” of international efforts “are also highly imbalanced.” The piece explains that “in some places, children’s health has improved drastically,” but “in others, many still die very early.”

HHS in the News

New York Becomes First State To Ban Sale Of Flavored E-Cigarettes.

ABC World News Tonight  (9/17, story 4, 0:55, Muir, 6.62M) reported that New York state approved “an emergency ban on sales of most flavored e-cigarettes, and it comes as we learn tonight of yet a seventh death now linked to vaping.”

The AP (9/17, Hajela, Klepper) reports that New York “became the first state to ban the sale of flavored e-cigarettes Tuesday, a move that comes as federal health officials investigate a mysterious surge of severe breathing illnesses linked to vaping.” The vote by the state Public Health and Health Planning Council “means the prohibition, which covers flavored e-cigarettes and other vaping products except for menthol and tobacco flavors, goes into effect immediately. Retailers will have two weeks to remove merchandise from store shelves.”

The Wall Street Journal (9/17, West, Subscription Publication, 7.57M) reports that some members of the council said they were conflicted about signing off on the emergency measure and others said they would have preferred that it include menthol flavoring.

CNN (9/17, Christensen, 83.16M) reports that the ban “would stand for 90 days as a piece of emergency legislation” and “would need to be renewed to continue.” The only two flavors customers “will be able to buy are

tobacco and menthol." New York state Health Commissioner Dr. Howard Zucker "said in the emergency meeting that officials would take a closer look at menthol to decide whether it should be banned as well."

The New York Post (9/17, Narizhnaya, Hogan, Fonrouge, 4.57M) reports that "the New York State Vapor Association, a trade group representing 700 independent vape shops across the state, held a series of events across the state announcing they're considering legal options to fight" the ban, which was proposed Sunday by Gov. Andrew Cuomo (D).

Also reporting on the story are: Reuters (9/18, Dobuzinskis), The Hill (9/17, Axelrod, 2.98M), Forbes (9/18, Lee, 9.71M), the Albany (NY) Times Union (9/17, Bump, 457K), the New York Post (9/17, Hogan, Fonrouge, 4.57M), the Lower Hudson Valley (NY) Journal News (9/17, Robinson, 328K), the New York Daily News (9/18, Shahrighian, 2.52M), and the Buffalo (NY) News (9/17, McNeil, 391K).

States, Localities Rush To Limit Vaping, But Experts Say Effect Uncertain. The New York Times (9/17, Williams, Del Real, 18.61M) reports, "After a spate of illnesses linked to vaping, states are rushing to push through bans on e-cigarettes for anyone under 21. Governors are calling for prohibitions on flavors like bubble gum, cotton candy and banana split, which critics say are meant to entice young people into trying vaping. And in some states, lawmakers are contemplating raising taxes on vaping products as a way to discourage their use. Yet amid the flood of new measures from state leaders as well as mayors, experts said it was uncertain how much immediate or lasting effect the provisions would have on a broad and growing range of concerns about vaping."

The Cleveland Plain Dealer (9/17, Hancock, 895K) reports that Ohio Gov. Mike DeWine (R) "said Tuesday his legal team is looking to see whether he has the authority to ban flavored e-cigarettes." DeWine "told cleveland.com, 'This is a public health crisis,' noting that more than a dozen Ohioans aged 16 to 26 have been hospitalized with severe lung disease because of vaping. Nationwide, seven people have died recently from a vaping-related illness."

Politico (9/17, Colliver, 4.29M) reports that several California cities "are swiftly moving beyond flavored vape bans to outlaw e-cigarette sales entirely, following in the footsteps of Juul's hometown of San Francisco." JUUL Labs "already has spent more than \$4.5 million trying to convince voters to overturn San Francisco's first-in-the-nation e-cigarette ban with a November ballot initiative." If San Francisco's broad ban "prevails at the ballot box, it will likely encourage more cities and states to take bold measures."

The Washington Post (9/17, Nirappil, 14.2M) reports DC lawmakers on Tuesday "proposed sweeping measures to curb the rise of youth vaping, including a ban on flavored e-cigarettes and requiring a prescription to buy other electronic smoking products." A bill "introduced by D.C. Council Member Vincent C. Gray (D-Ward 7) would ban the sale of vaping products at any location that is not a medical marijuana dispensary or a pharmacy. The District would be the first U.S. jurisdiction with such stringent restrictions on e-cigarette sales."

JUUL Product Sales Halted In China Days After They Were Launched. The Wall Street Journal (9/17, Maloney, Subscription Publication, 7.57M) reports that sales of JUUL Labs products in China have been halted just days after they launched on ecommerce sites JD.com and Tmall. Juul representatives said they are in contact with the sites' owners but don't know why sales were stopped.

Bloomberg (9/17, Huet, 4.73M) reports the company "said it wants to make the products available again in the world's largest tobacco market." Victoria Davis, a spokeswoman for Juul, said in an emailed statement: "We

remain steadfast in our commitment to providing the more than 300 million adult smokers in China with a viable alternative to combustible cigarettes.”


Reuters (9/17, Soundarya, Kirkham) reports that the company “is aggressively expanding in international markets including China.”

Forbes (9/17, Voytko, 9.71M) reports, “There are over 300 million smokers in China, and nearly 60% are male, according to the World Health Organization. In 2018, around 2.4 trillion cigarettes were sold in the country through China National Tobacco, a state-run monopoly.”

US, UK View Vaping Very Differently. CNN (9/17, Hunt, 83.16M) reports that while the Trump Administration has “moved to ban e-cigarette flavors and there are warnings to avoid vaping altogether,” in the UK, e-cigarettes “have been embraced mostly as a way for adults to quit combustible cigarettes. Indeed, health authorities in the UK stand by their support for e-cigarettes as a cessation tool.” The difference in attitude appears to be related to “regulation, especially on advertising and promotion, and the levels of nicotine in vaping products.”

Policy Expert Argues Market Model For Vaping, Marijuana Harms Young People. In an opinion piece for The Hill (9/17, 2.98M), Meryl Justin Chertoff, the incoming Executive Director of the Georgetown Project on State and Local Government Policy and Law, writes that “rather than limiting access using a medical model – allowing vaping only by prescription and with strict controls against youth use – vaping was introduced on a market model,” and the “marketing appears to have been targeted at young people.” Chertoff says “laxity by state regulators and legislators has allowed the industry to market e-cigarettes to American kids,” resulting in “apparent vaping-related deaths and lung damage to young people and a new generation with an addiction problem.” Chertoff adds that “states also should be reviewing their pot laws, reconsidering the wisdom of letting markets compete for use by teenagers.”

Seventh Person Dies From Lung Illness Tied To Vaping.

NBC Nightly News  (9/17, story 4, 1:25, Holt, 5.96M) reported on “the death of another patient from a serious illness related to vaping.” The California man, aged 40, died from severe pulmonary injury, according to health officials. It is the seventh reported death from lung illness tied to vaping. Currently, “the CDC is investigating 380 cases across 36 states, and has activated its emergency operation center, directing more staff and resources to the problem.”

The Washington Post (9/17, Epstein, Sun, 14.2M) reports “the unnamed Tulare County man died of ‘complications related to the use of e-cigarettes,’ according to the county Health and Human Services Agency.” The patient “had been in the hospital for ‘several weeks’ before his death, said department spokeswoman Jan Winslow.” The man “had a history of vaping, though Winslow said officials were still investigating what products he used.”

Two More Cases Of Vaping-Related Lung Disease Identified In Washington State. The Oregonian (9/17, Zarkhin, 1M) reports that “two new cases of the severe lung disease related to e-cigarettes have been identified in Washington, raising the number of victims in that state to three, health officials said Tuesday.” The victims were “both in Spokane County” and were both “young – one patient was under 20 and another was between 20 and 29 years old.” Still, “no specific product or device has yet been identified, according to the Washington State Department of Health.”

The Seattle Post-Intelligencer (9/17, Guevara, 430K) reports Washington State Health Officer Kathy Lofy said in a news release, "This is now a state-wide outbreak." The patients "all exhibited symptoms indicating lung disease and reported vaping before becoming sick."

Two More Cases Of Vaping-Related Respiratory Illness Reported In Oregon. The AP (9/17) reports that "state officials say two additional cases of respiratory illnesses linked [to] vaping have been reported, bringing the total number of cases in Oregon to four." The new cases follow state health officials' announcement "that an Oregonian died in July from a respiratory illness tied to vaping." Officials have not "provided details about the three other people's illnesses or where they were treated."

Arizona Identifies Three Cases Of Vaping-Related Respiratory Illness. The AP (9/17) reports that Arizona "health officials say three cases of vaping-related respiratory illness have been identified in" the state, all in Maricopa County. According to the state Department of Health Services, "the people involved in all three cases in Arizona were hospitalized but have since been discharged." The AP adds that the federal CDC "says investigators haven't any specific substance or vape product linked to all cases."

The Arizona Republic (9/17, Innes, 869K) reports that "in all three cases, the patients were males in their 20s." A Maricopa County Department of Public Health spokeswoman "said in the local cases, the patients vaped products with nicotine and cannabinoids."

Vermont Confirms First Case Of Severe Respiratory Illness Linked To Vaping. The Burlington (VT) Free Press (9/17, Syed, 125K) reports that Vermont's "health department confirmed its first case of severe respiratory illness associated with vaping." Currently, "investigations are underway regarding five more potential cases."

VT Digger (VT) (9/16, French, 4K) also reported on the story.

Pulmonologist Documented Case Of Vaping-Related Pneumonia Eight Years Ago. The Portland (OR) Business Journal (9/17, Hayes, Subscription Publication, 827K) reports that "eight years ago, long before the current health scare from e-cigarettes, a pulmonologist...documented a case of vaping-related pneumonia." A woman, aged 42, was admitted to a hospital "after shortness of breath, cough and fevers." The woman's "respiratory symptoms had started about seven months earlier, when she began using e-cigarettes." She "had lipoid pneumonia," and "the suspected source was 'recurrent exposure to glycerin-based oils found in e-cigarette nicotine vapor,' according to" a study published in the journal Chest.

Boston Doctors Believe Vaping Crisis Is Being Under-reported. The Boston Globe (9/17, Martin, 972K) reports Boston Children's Hospital has seen seven patients "over the past year and a half believed to be suffering from vaping-related lung illness that has recently roiled the country, leaving seven dead and 380 hospitalized." According to the article, "the exploding outbreak, linked to 38 possible cases in Massachusetts, has raised questions about why it's happening now, when vaping has been popular for years." Doctors in the Boston area "believe the vaping-related lung injuries have been going on much longer and affected far more people than officially reported." They point to "a host of reasons for the current crisis: toxic chemicals in the supply chain of vape products; clinicians previously only asked patients about cigarettes, not vaping; and more people are vaping now."

Azar Met With Ugandan Minister Of Health.

Eagle Online (UGA) (9/17, Serugo) reports in continuing coverage that HHS Secretary Azar “has met with the Ugandan Minister of Health Jane Aceng and toured key public health response centers.” Azar and Aceng “discussed the Ugandan government’s successful response to recent isolated cases of Ebola in the country, and ongoing efforts to control the spread of the Ebola outbreak.” Minister Aceng also “hosted Secretary Azar...on a tour of the Uganda National Institute of Public Health, including the Public Health Emergency Operations Center and the Field Epidemiology Training Program, a program supported by the Centers for Disease Control and Prevention.” The piece adds that Azar “also visited the Uganda National Health Laboratory Service (UNHLS),” and “Secretary Azar spoke with Minister Aceng and UNHLS officials about how the U.S. government can continue to support research at the UNHLS.”

PML Daily (UGA) (9/18) reports “Azar assured President Museveni of the USA’s continued support to Uganda in combating infectious diseases.” The piece says that “Museveni [appreciates] the USA’s role” because through the US CDC, “Uganda is able to obtain a modern laboratory.”

Azar Asks Tanzania For Transparency On Case Of Woman Who Died From Unknown Illness.

The Daily Nation (KEN) (9/17, Merab, 5K) reports in continuing coverage that on Monday, HHS Secretary Azar “asked [the] Tanzanian government to disclose information about a woman who died from what the World Health [Organization] termed as an unknown illness.” Azar added that Tanzania “has refused to avail samples from the deceased for testing, nor has it made available other information about them.”

Azar Led Delegation To Ebola Treatment Center In DRC.

Homeland Preparedness News (9/17, Kovaleski) reports HHS Secretary Azar “led a contingent of U.S. officials on a tour last week of an Ebola treatment center” in Butembo, Democratic Republic of the Congo, “observed the detection, infection prevention, and control measures,” and “shared his sincere gratitude for the hard work and dedication all personnel have shown in the face of this health crisis.”

Some Brokers Selling Poor Insurance Policies Under ACA Exemptions.

Bloomberg (9/17, Darie, 4.73M) reports that “some brokers are taking advantage” of changes to health insurance rules made by the Trump Administration, “selling plans so skimpy that they offer no meaningful coverage.” Bloomberg quotes HHS Secretary Azar as saying, “These plans aren’t for everyone, but they can provide a much more affordable option for millions of the forgotten men and women left out by the current system.” Bloomberg cites Health Insurance Innovations as “the center of the market.” The company, Bloomberg says, “sought to provide a clearinghouse for brokers who sold cheap insurance to individuals.” Bloomberg focuses on the experience of one couple who bought a policy that paid just \$4,000 for heart surgery, leaving them with bills of over \$200,000, and, Bloomberg adds, “similar stories aren’t hard to find.” Bloomberg also reports that the couple now has “a comprehensive, ACA-compliant insurance policy” that “costs less than they were paying for junk insurance.”

Tennessee Proposes Block Grant Reform For Medicaid.

The Washington Post (9/17, Goldstein, 14.2M) reports, “Tennessee unveiled a plan on Tuesday to convert Medicaid into a block grant” which has been “long supported by conservatives,” but which the Post says “would

rupture the federal government's half-century-old compact with states for safety-net insurance for the poor." CMS Administrator Seema Verma, the Post adds, "has urged states to move toward block grants." Tennessee is the first state to submit a block grant proposal. Under its proposal, TennCare, the state's Medicaid program, would use a block grant "for medical services for children, pregnant women, parents and other core groups of people such as those who are blind and disabled," while "coverage of prescription drugs and payments to hospitals that treat a large share of low-income patients" would not be affected. Under the proposal, "if the state spent less in a given year than it would have under the traditional Medicaid system, Tennessee would split those savings" with the federal government.

The Wall Street Journal (9/17, Armour, Subscription Publication, 7.57M) reports Tennessee Gov. Bill Lee (R) told the Journal the state intends to follow Administration policy in seeking greater innovation of services and efficiency. The Journal adds that Tennessee's draft proposal will have a comment period and a final proposal will be submitted in November.

CNN (9/17, Luhby, 83.16M) reports on its website that CMS spokesman Johnathan Monroe said, "CMS supports efforts to improve accountability for cost and outcomes in Medicaid, and we look forward to working with Tennessee once they submit their proposal to help them achieve these goals as effectively as possible within our statutory authority."

The Chattanooga (TN) Times Free Press (9/17, Sher, 171K) reports Tennessee estimates the block grant would be "a \$7.9 billion annual lump sum," and promises "to share future anticipated savings in TennCare on a 50/50 basis with the federal government." Lee believes the proposal "could provide upwards of \$1 billion for Tennessee" that could be used for "health care, including rural health initiatives," or for "select expansion of TennCare to new population categories." Tennessee will hold "three public hearings in each of the state's three grand divisions in the cities of Knoxville, Nashville and Jackson." The Times Free Press adds, "A 30-day public comment period is in place before the actual Medicaid Section 1115 waiver for TennCare can be submitted to federal officials."

The Hill (9/17, Weixel, 2.98M) reports HHS Secretary Azar "told lawmakers last spring that he had been having conversations with states interested in the idea."

CQ Roll Call (9/17, Raman, 154K) reports, "Under the state's waiver plan, Tennessee would gain the flexibility to adjust its Medicaid program in new ways without needing federal approval for each change," though it "would not change who is eligible for some types of coverage or which benefit categories are offered under Medicaid."

The Daily Memphian (TN) (9/17, Stockard) reports, "Congress has not approved a block grant program, and there's no guarantee the feds will agree to share any savings the state finds."

Modern Healthcare (9/17, Luthi, Subscription Publication, 214K) reports, "patient advocates are blasting" the proposal "as undercutting core guarantees for patients without any accountability."

The Nashville (TN) Business Journal (9/17, Stinnett, Subscription Publication, 844K) reports Gov. Bill Lee "said the state has spent less than projected in each of the last 10 years."

The Tennessean (9/17, Allison, 458K) reports, "The savings estimate is based on recent data on annual spending by TennCare."

FierceHealthcare (9/17, King, 146K) reports Tennessee said the plan "does not rely on reductions to eligibility or benefits in order to achieve savings."

Axios (9/17, Ayesh, Owens, 521K) says that if it is approved and implemented, it “would be a radical change to the medical safety net for the nation’s poorest citizens.”

The Fiscal Times (9/17, 3K) also reports on the story.

FDA Hosts Public Hearing To Discuss Standards For Future Opioid Analgesic Approvals.

Politico (9/17, Oweremohle, 4.29M) reports in its Prescription PULSE section that the FDA hosted a public hearing yesterday “to discuss standards for future opioid analgesic approvals, along with incentives for new (and non-opioid) pain and addiction medicines.” At the event, Public Citizen’s presenter spoke on the FDA’s “Woefully Inadequate in Substance, Devoid of Necessary Urgency” opioid framework. Also, “pharmaceutical companies and the trade group BIO will also weigh in on incentives – or lack of them – to make new pain options.”

Roche’s Obinutuzumab Receives FDA Breakthrough Therapy Designation For Lupus Nephritis.

Reuters (9/18, Miller) reports Roche has been awarded “the U.S. Food and Drug Administration’s breakthrough therapy tag for its drug Gazyva [obinutuzumab] in lupus nephritis, the Swiss drugmaker said on Wednesday, boosting its efforts to recycle the 2013-approved lymphoma medicine for new indications.” Currently, “there are no FDA-approved drugs for lupus nephritis, a life-threatening manifestation of the autoimmune disease lupus in which the kidneys grow inflamed.” Sandra Horning, Roche’s Chief Medical Officer, said, “We are committed to developing Gazyva as a potential new therapy for lupus nephritis and plan to begin enrolling patients in a phase III trial next year.”

Hospitals Challenge HHS Regulation That Reduces Funding For Hospitals Training Medical Fellows.

Bloomberg Law (9/17, Pazanowski, Subscription Publication, 4K) reports 32 hospitals have filed a lawsuit against the Department of Health and Human Services seeking “to invalidate a new regulation that reduces the money they receive for training medical fellows.” The hospitals claim that the “new regulation imposes a ‘fellow penalty’ on hospitals that receive compensation for the part of the costs they incur in training residents that is attributable to treating Medicare beneficiaries.”

Federal Judge Tosses Out CMS Action On Hospital Outpatient Payments.

Bloomberg Law (9/17, Wheeler, Pugh, Subscription Publication, 4K) reports behind a paywall that a federal district court judge in the District of Columbia “tossed out a Trump administration scheme that lowered how much off-campus, hospital-based clinics can get paid for treating Medicare patients.” The US District Court for the District of Columbia “said the Centers for Medicare & Medicaid Services, part of the Department of Health and Human Services, ‘exceeded its statutory authority when it cut the payment rate for clinic services at off-campus provider-based clinics.’”

Columnist Argues Right-To-Try Erodes Authority Of FDA And Undermines Public Health.

Michael Hiltzik writes in his daily business column for the Los Angeles Times (9/17, 4.64M), “The federal right-to-try law, signed by President Trump in May 2018...always was a cruel sham perpetrated on sufferers of intractably fatal diseases.” Although, Hiltzik adds, “the law was promoted as a compassionate path to experimental

treatments for those patients,” it was, he says, “a cynical ploy aimed at emasculating the Food and Drug Administration in a way that would undermine public health and harm all patients.” Hiltzik also accuses President Trump of “making up claims about the law,” and doing so during a “White House event on Sept. 11...while Health and Human Services Secretary Alex Azar and Acting FDA Commissioner Ned Sharpless sat silently by nearby.” Hiltzik concludes, “right-to-try was the first step in eroding the authority of one of the nation’s most important agencies safeguarding public health.”

National Front Page News

Headlines From Today’s Front Pages.

Wall Street Journal:

Saudi Arabia Set To Return To Normal Oil Production Levels By End Of Month

Fed Intervenes To Curb Soaring Short-Term Borrowing Costs

Streaming War Spurs Classic TV Arms Race

‘Nobody Has To Be Punished’: Joe Biden’s Economic Tap Dance

Spotted Lanternfly VS. Pennsylvania: The Bug Is Winning

New York Times:

After Tight Israeli Election, Netanyahu’s Tenure Appears Perilous

Trump To Revoke California’s Authority To Set Stricter Auto Emissions Rules

To Find Clues In Saudi Oil Attacks, US Examines Missile And Drone Parts

Trump’s Challenge: Can His Word On Iran Be Trusted?

Cokie Roberts Dies; Veteran Broadcast Journalist Was 75

Almost Everywhere, Fewer Children Are Dying

Washington Post:

Pompeo flying To Mideast For Talks

EPA To Curtail Calif. Air Rules

Pioneer, Champion Of Women In Media

Vaping Industry Goes Into Crisis Mode After Trump Ban

New Focus On Crowd Size As Warren Rally Rivals Trump’s

In Israeli Exit Polls, No Clear Winner

Financial Times:

Johnson To Abide By Any Supreme Court Ruling On Recalling MPs

Bill Gates: Fossil Fuel Divestment Has ‘Zero’ Impact

Saudi Oil Attack Highlights Middle East’s Drone War

Fed Plans Second Intervention To Ease Funding Squeeze

Washington Times:

Trump Rejects Iran Meeting, Looks Past Sanctions To 'Restore Deterrence'

Iran Clash Distracting Trump From Advancing North Korea Nuke Deal, South Korea Officials Fear

Defiant Lewandowski Infuriates Dems, Delights Trump: 'Thank You, Corey'

Top Democrats Rush To Squash Kavanaugh Impeachment Push

IG Report Details Andrew McCabe's FBI leaks, Secretive Media Campaign And Cover-Up

Story Lineup From Last Night's Network News:

ABC: Tropical Storm Imelda; Teens Arrested For High School Shooting Plot; MLB-Pittsburgh Pirates Pitcher Arrested; New York-Flavored E-Cig Ban; Saudi Arabia-Oil Facility Attack; Corey Lewandowski-Testifying On Capitol Hill; Remembering Cokie Roberts; Alex Trebek Interview; NYC-Domestic Call Turns Into Shootout; Montana-Grizzly Bear Attack; Potential Cure For Common Cold; Cokie Roberts-Her Own Words.

CBS: Tropical Storm Imelda; Saudi Arabia-Oil Facility Attack; Mike Pompeo-Saudi Arabia Trip; Afghanistan-Green Beret Killed In Combat; Afghanistan-Suicide Attacks; Syria-ISIS Fighters; Israel-Election; Corey Lewandowski-Testifying On Capitol Hill; MyPayrollHR Shutdown; UN-Climate Crisis Summit; Colorado Woman Swims Across English Channel Four Times; Remembering Cokie Roberts.

NBC: Tropical Storm Imelda; Saudi Arabia-Oil Facility Attack; Israel-Election; New York-Flavored E-Cig Ban; Afghanistan-Green Beret Killed In Combat; Teens Arrested For High School Shooting Plot; Corey Lewandowski-Testifying On Capitol Hill; Amazon-Job Fairs; Remembering Cokie Roberts; Climate Change-Warming Waters; MyPayrollHR Shutdown; NFL-Antonio Brown; Colorado Woman Swims Across English Channel Four Times.

Network TV At A Glance:

Remembering Cokie Roberts – 7 minutes, 45 seconds

Saudi Arabia-Oil Facility Attack – 6 minutes, 20 seconds

Tropical Storm Imelda – 3 minutes, 45 seconds

Corey Lewandowski-Testifying On Capitol Hill- 3 minutes, 40 seconds

Story Lineup From This Morning's Radio News Broadcasts:

ABC: Corey Lewandowski-Testifying On Capitol Hill; Mike Pompeo-Saudi Arabia Trip; New York-Flavored E-Cig Ban; Teens Arrested For High School Shooting Plot.

CBS: Mike Pompeo-Saudi Arabia Trip; Tropical Storm Imelda; GM-Strike; Corey Lewandowski-Testifying On Capitol Hill; Remembering Cokie Roberts.

FOX: Corey Lewandowski-Testifying On Capitol Hill; New York-Flavored E-Cig Ban; Hurricane Humberto.

NPR: Mike Pompeo-Saudi Arabia Trip; Israel-Election; US Abortion Rates Down; New York-Flavored E-Cig Ban.

Last Laughs

Late Night Political Humor.

Trevor Noah: [On Sean Spicer's performance on 'Dancing With The Stars'] "Let's kick it off with Sean Spicer, former press secretary and human Dilbert. Like most people President Trump hires, Spicer left the administration with his reputation in tatters. But if there's one thing American loves, it's a comeback. ... It sounded like the

judges did not like Spicer's dancing, or at least that's how last night. But today, Sean Spicer said it was actually the best performance they had ever seen of all time."

Trevor Noah: "Honestly, I think Spicer will be perfect for 'Dancing With The Stars.' Yeah, pretend you know what you're doing till you get kicked out. It's just like working for Trump."

Trevor Noah: "The presidential race. Even though we have been in primary season for six years, we're still 11 months away from seeing one Democrat face off against Donald Trump. But last night, we might have got an sneak peek to the general election, because last night, Elizabeth Warren and Donald Trump held dueling campaign rallies on opposite sides of the country."

Trevor Noah: "So let's start with Elizabeth Warren, Massachusetts Senator and mom who knows all the two-letter words in Scrabble. ... After her speech, Elizabeth Warren spent four hours taking selfies with her supporters. It took three hours to get most of the crowd, and then an extra hour for that one annoying person who's never satisfied. 'Oh, no, wait, I look weird. Do it again. Let's try portrait mode. Now one with funny faces. Aaaahhh! Oh, memory is full, let me delete a podcast, hold on, hold on.'"

Trevor Noah: [On Trump's rally, asking Steve Cortes about loving the country and Hispanics] "While Elizabeth Warren was taking over New York, Donald Trump was doing his campaign rally in New Mexico, a solidly blue state with a Hispanic population, which is probably why he tried to tailor his speech to the crowd, and it got a little uncomfortable. ... What...was that? 'What do you like more, the country or Hispanics?' Those two things aren't even in the same category! What do you like better, Pepsi or Mongolia, huh? It's also a [bad] question, because it implies that Hispanics aren't a part of the country, right? And what's amazing is, it was still somehow only the second-most-offensive thing Trump said...because Trump also said he was confused by his Hispanic friend who looks too white. He said, 'I don't get it, how come you're not wearing a sombrero or dancing the salsa? You're less Hispanic than Sean Spicer!'"

Trevor Noah: "Am I the only person who feels Donald Trump uses these rallies as his personal therapy sessions? Pretty soon he's just going to come out on a couch telling us his pain. (As Trump) 'Who here wasn't hugged by their father? What do you like more, Hispanics or your fear of dying alone?'"

Conan O'Brien: "True story: Today, President Trump visited Los Angeles in an attempt to raise money for his 2020 re-election campaign. He's in town raising money, that's right. Ladies and gentlemen, he raised \$48."

Jimmy Kimmel: "Welcome to Los Angeles, California, where the traffic today is even more terrible than the usual terrible because we have a special visitor in town. You know? We're at Code Orange right now, because President Trump is here. It's weird to think that right now, the President of the United States is lurking just a few miles away from here in his hyperbaric tanning chamber, eating all our Popeye's chicken sandwiches, but he is."

Jimmy Kimmel: "Trump is at a fundraiser in Beverly Hills and had a meet-and-greet in Palo Alto where tickets went up to \$100,000. You get a round table discussion, a photo op, and what they billed as premiere seating for lunch. What is 'premiere seating for lunch' with Donald Trump? You get to join him in his booth at Carl's Jr.?"

Jimmy Kimmel: [On Trump's rally, asking Steve Cortes about loving the country and Hispanics] "Our traffic-cone-in-chief was in New Mexico last night for a rally that celebrated his version of diversity. ... 'There's nobody that loves Hispanic more.' I know he doesn't speak Spanish, but now he's not even speaking English."

Jimmy Kimmel: "The Democrats still aren't fully on board with impeachment, because they know no matter what happens in the House, Trump will be saved by the Republican Senate. So a lot of them say, 'What's the point?' This is the point: A move to impeach Donald Trump would go on for months. This would be hours and hours of hearings and televised testimony, all for our couch potato President to take in. He'll be so busy watching and tweeting about it, and just maybe, he'll forget all the other terrible things he wants to do. Impeachment is a good way to distract Donald Trump with the subject he cares about most, which is Donald Trump. Basically, our President is an unruly child throwing a tantrum while we try to eat dinner at a restaurant, and impeachment is an iPad loaded with 'Paw Patrol.' So I say, send in Ryder and his team of pups, and let's see what happens."

Jimmy Kimmel: [On Sean Spicer's performance on 'Dancing With The Stars'] "Somehow 'Dancing With The Stars' found a way to humiliate Sean Spicer more than the President of the United States."

Stephen Colbert: "[Trump] is at fundraisers today in Silicon Valley and Los Angeles. But because he's so unpopular in California, the events were shrouded in secrecy. In fact, attendees at Tuesday's event were not even provided with the address of the lunch. Though, it is easy to find Trump's lunch -- just follow the trail of ketchup packets and Filet-o-Fish wrappers."

Stephen Colbert: "Still, the events sold out in a hurry. According to one California Republican, 'They're excited because we've had surrogates like Don Jr. come out. But this is the real thing.' Yeah! The real thing! Hollywood wants to see the special effects that make Trump seem so lifelike."

Stephen Colbert: "Now Trump, of course, is a TV guy. So it's no coincidence that his LA fundraiser is taking place during Emmy week. He is up for outstanding achievement in visual effects for Sharpie on a weather map."

Stephen Colbert: "Now, I can understand going to Los Angeles. He's not popular there, but Hollywood is a thin layer of dirt scattered over a pool of money. Everyone wants to get their drill bit through that crust into that sweet bubblin' cash crude. They're largely liberal, but there's enough money that everyone, no matter how horrible, gets funded. Trump is, let's say, 'The Emoji Movie' of candidates."

Stephen Colbert: "[Trump's] internal polling must be terrible, because he is reaching out to people who want nothing to do with him. And this time, it's not Melania. ... Last night, the President held a rally in a state he lost last time by eight points, New Mexico. ... After four years of Donald Trump throwing Latinos under the bus that he stopped at the border, by saying that illegal and legal immigrants are all coming to kill us, Trump's plan to win is to woo Hispanic voters. Woo, boy. Buena suerte with that, El Trumpo."

Stephen Colbert: "Right now, Trump's approval rating among Hispanics is 25 percent. So, this is like Cruella De Vil trying to woo Sarah McLaughlin."

Stephen Colbert: "Trump must really need los hombres hispanico because he laid it on muy thick ... Always a good sign, asking minorities to identify themselves. (As Trump) 'Okay, who here is Latino? Raise your hands. Whoa. I can't believe you fell for that. Round 'em up, boys!'"

Stephen Colbert: "But Trump wasn't the only one rallying last night. So was Massachusetts Senator...Elizabeth Warren. ... Last night, she held a rally in New York's Washington Square Park, which drew a crowd of 20,000 people! Yeah, 20,000! ... Only 3,000 of which were there to score weed."

Jimmy Fallon: "Well, you guys, last night, the Jets lost to the Browns on Monday night football 23-3, and it was embarrassing and hard to watch, just like Sean Spicer on 'Dancing With The Stars.'"

Jimmy Fallon: "That's right, Sean Spicer made his debut on 'Dancing With The Stars' last night. It was so bad, the judges actually turned their chairs around like 'The Voice.'"

Jimmy Fallon: "A lot of people weren't happy that Spicer was given a spot on 'Dancing With The Stars' due to his role in the Trump Administration. We got to be careful, or we'll tarnish the great American institution, 'Dancing With The Stars.'"

Jimmy Fallon: "Today, Trump held a fundraiser in California, where he has some of his worst approval ratings. It's bad. When Trump drove by Disneyland, Mickey Mouse said if he had a middle finger, he'd be using it."

Jimmy Fallon: "Last night, Elizabeth Warren held a massive rally right here in New York City. ... That's right, Warren was so popular, the only way police could get everyone to leave was by saying, 'Ladies and gentlemen, please welcome New York City Mayor Bill de Blasio.'"

Jimmy Fallon: "And Warren wasn't the only Democrat in the park. Bernie Sanders was also there on a bench feeding the pigeons, and muttering to himself, 'The top one percent get all the bread crumbs.'"

Seth Meyers: "According to fact checkers, President Trump made at least 26 false statements last night during his rally in New Mexico, and that was just during the sound check."

Seth Meyers: "President Trump watched his former campaign manager Corey Lewandowski's congressional testimony today from aboard Air Force One. And when you're trying to prove you're not a criminal, it doesn't help that your boss is watching from the getaway car."

Seth Meyers: "During an event in South Carolina yesterday, Republican presidential challenger Mark Sanford held a mock debate against a cardboard cutout of President Trump. You could tell the cutout wasn't the real Trump, because it made some good points."

Seth Meyers: "Following her rally in New York last night, Sen. Elizabeth Warren spent four hours taking selfies with supporters. Meanwhile, Bernie took one selfie that lasted four hours because the camera was accidentally set to video."

James Corden: [On Trump saying that Steve Cortes looks “like a WASP”] “President Trump had another one of his giant rallies last night, this time in New Mexico as an outreach to Hispanic voters. And at the rally, Trump referenced CNN contributor and Trump supporter Steve Cortes, who was just offstage. ... So, in Trump’s mind, the highest compliment he can give is, ‘I like you, Steve. You could pass for a white guy!’”

James Corden: “Trump on his absolute best behavior still talks about race like it’s fantasy football. Trump asked Steve Cortes, ‘Who do you like more, the country or the Hispanics?’ Coincidentally, that’s also the first and only question asked in a White House job interview.”

James Corden: “In other White House news, for the first time in history, the Secret Service has now formally requested – and we’re not making this up – they’ve formally requested jet skis. They say they need them because the Trump family spends a lot of time vacationing out on the water. ... The Secret Service said they need the jet skis to protect the first family. You know, from rogue Frisbees or any other dangers commonly found in a ‘90s beer commercial.”

James Corden: “This is true. The Secret Service only asked for two jet skis. They didn’t want to blow their whole budget because they’re saving up to buy a monster truck.”

National News

Trump: California Cities “Destroying Themselves” With Homelessness.

President Trump’s comments about homelessness in California, made before his arrival, receive more national media attention than his fundraising events in the state. The [San Francisco Chronicle](#) (9/17, Wildermuth, 2.67M) reports Trump “made his first visit to the Bay Area on Tuesday since taking office, raising money, dodging protesters and, shortly before landing, warning that San Francisco and other California cities were ‘destroying themselves’ with homelessness.” On Air Force One en route to California, the President told reporters, “Hundreds and hundreds of tents and people living at the entrance to their office building. And they want to leave. And the people of San Francisco are fed up, and the people of Los Angeles are fed up. And we’re looking at it, and we’ll be doing something about it.” The President “didn’t venture what that might be, other than to say he was looking into the creation of an ‘individual task force’ and talking with [HUD Secretary Carson] ‘in terms of the housing element.’”

The [Los Angeles Times](#) (9/17, Oreskes, Rust, Shalby, Cosgrove, 4.64M) reports, “In recent months, Trump has used the issue of homelessness to bash” California. State officials “have been wary of the Trump administration’s intentions, concerned that the president wants to use homelessness and urban ills as a wedge for the 2020 campaign. But they have said that they are willing to work with Trump.” [USA Today](#) (9/17, Collins, Fritze, 10.31M) reports Trump “previously has described California’s homeless problem as ‘disgusting’ and a ‘disgrace to our country.’” USA Today says Trump “routinely slams the policies” of the “overwhelmingly Democratic” state.

The [New York Times](#) (9/17, Dougherty, 18.61M) reports, “Numerous protesters and politicians said they found Mr. Trump’s sudden interest in homelessness to be disingenuous and an example of the administration trying to score political points at the state’s expense instead of actually grappling with a humanitarian crisis that

has become the driving political issue in state and local politics.” The Washington Post (9/17, Dazio, 14.2M) reports Trump “began a California visit on Tuesday, saying he will do ‘something’ about homelessness but offering no specifics beyond the mention of creating a task force.” Los Angeles Mayor Eric Garcetti “said he would welcome Trump’s help to end homelessness if he contributed federal dollars or property that could be converted into shelters.”




The San Francisco Chronicle (9/17, Fagan, 2.67M) – writing that “he came, he saw, he offered nothing specific” – reports Carson “paid a quick visit to a public housing project in Potrero Hill, dodged an invitation to meet with the mayor, and left – all in the space of about an hour.” His “purpose in visiting the housing project was to ‘listen’ and gather facts, Carson said.” The San Francisco Examiner (9/17, Waxmann, 438K) reports Carson “echoed calls by a White House committee to deregulate the housing market and increase policing.” Carson said, “Evidence shows us quite clearly that the places that have the most regulation also have the highest prices and the most homelessness. Therefore it would seem only logical to attack those things that seem to be driving the issues.”

Rep. Barbara Lee (D-CA) tweeted, “If Trump is serious about addressing homelessness, he needs to quit the cuts to programs that keep people housed and invest in the things we know help families keep a roof over their heads.”

Ex-Rep. Beto O’Rourke (D-TX) tweeted, “This is classic Trump. He’s going to terrorize homeless Americans because he thinks they can’t fight back. They deserve shelter. They deserve affordable housing. They deserve mental health care. And most of all they deserve dignity.”

Protesters Assemble Near Trump Fundraising Events. The AP (9/18, Slodysko, Slodysko, Freking, 12.82M) says Trump “rarely passes up the chance to throw a sharp elbow at left-leaning California, but he showed Tuesday he’s more than happy to cash in there with a lunch-dinner-breakfast-lunch fundraising blitz expected to scoop up \$15 million from wealthy Republicans in two days.” The East Bay Times (9/17, Woolfolk, 63K) reports Trump appeared at “a high-dollar fundraiser at the home of a former technology executive in the hills above Palo Alto...with tickets ranging from \$1,000 to \$100,000.” The President later attended “other fundraising events in Los Angeles and San Diego.”

The San Francisco Chronicle (9/17, Serrano, 2.67M) reports protesters turned out near the home of Sun Microsystems co-founder Scott McNealy, host of the Palo Alto event. The San Francisco Chronicle (9/17, Garofoli, 2.67M) says McNealy “is one of the few tech titans who have consistently supported the president.” Bay City News Service (9/17, Service, 80K) reports, “Protesters with activist groups like the Backbone Campaign and Raging Grannies went alongside a road in Portola Valley with colorful inflated balloon versions of Trump to look like a baby and a chicken. The activists also were handing out stickers calling for Trump’s impeachment.”

KTVU-TV  San Francisco (9/17, 6:03 p.m. PDT, 41K) reported, “Protesters gathered, some holding signs and banners that expressed their anger.” KABC-TV  Los Angeles (9/17, 6:00 p.m. PDT, 246K) reported there were also demonstrators near the President’s Beverly Hills fundraiser at the home of real estate developer Jeffrey Palmer. KCBS-TV  Los Angeles (9/17, 6:00 p.m. PDT, 109K) also focused its report largely on the demonstrations.

EPA Expected To Revoke California’s Authority To Set Stricter Fuel Efficiency Standards. Reuters (9/17, Shepardson) reports the Trump Administration “will announce as early as Wednesday it is

revoking California's authority to set its own greenhouse gas and vehicle fuel efficiency standards and barring all states from setting such rules, two auto industry officials said on Tuesday." The Los Angeles Times (9/17, Phillips, 4.64M) reports the President "is expected on Wednesday to revoke a decades-old rule that empowers California to set tougher car pollution standards than those required by the federal government – putting the state and the [EPA] on a path to years of fighting in court."

The San Jose Mercury News (9/17, Rogers, 456K) reports EPA officials "declined to comment," but EPA Administrator Wheeler "told the National Automobile Manufacturers Association Tuesday: 'We will be moving forward with one national standard very soon.'" The Washington Post (9/17, Eilperin, Dennis, 14.2M) says the move "is likely to be unpopular nationwide and in California, with Americans widely supportive of stricter fuel efficiency standards. A Washington Post-Kaiser Family Foundation poll released Friday found 66 percent of Americans oppose Trump's plan to freeze fuel efficiency standards rather than enforce the Obama administration's targets for 2025."

The Sacramento Bee (9/17, Kasler, Wilner, 567K) reports Gov. Gavin Newsom (D) said California will "fight this latest attempt and defend our clean car standards." Newsom tweeted, "Fact is, CA's outperforming the federal government: Running record surpluses while Trump runs record deficits. Meeting our climate goals while expanding our economy. We're the progressive answer to a transgressive President – and it's driving him mad." The New York Times (9/17, Davenport, 18.61M) reports California Attorney General Xavier Becerra (D) "wrote in an email: 'California will continue its advance toward a cleaner future. We're prepared to defend the standards that make that promise a reality.'"

Politico (9/17, Guillén, 4.29M) says it "first reported earlier this month that the Trump administration planned to sever and advance the portion of its auto emissions rollback targeting California from the broader, more technical rulemaking setting new national standards for model year 2021 vehicles and beyond." The Hill (9/17, Green, 2.98M) also has a report.

Rep. Brad Sherman (D-CA) tweeted in response to the plan, "Outrageous. A blow to our environment. A blow to American energy independence. A boon to those who benefit from higher oil prices, like #Venezuela & #Iran."

Fed Intervenes To Keep Rates From Rising Above Target For First Time Since 2008.

The New York Times (9/17, Smialek, 18.61M) reports that the Federal Reserve on Tuesday "had to step into financial markets...to keep interest rates from rising above its target, the first time the central bank has had to carry out this type of 'market operation' since the global financial crisis." The Times says the Federal Reserve Bank of New York "had to spring into action to keep the effective fed funds rate in line after it rose to the very top of the Fed's 2 to 2.25 percent range." According to the Times, "Tuesday's intervention is symbolically important. The central bank decided just this year to keep its balance sheet large enough that it can set its policy rate without active market operations. But this episode suggests that it may not have kept its holdings big enough for that approach to work amid more extreme market conditions."

The Wall Street Journal (9/17, A1, Timiraos, Kruger, Subscription Publication, 7.57M) reports on its front page that the Fed on Tuesday morning injected \$53 billion into the banking system through transactions known as repurchase agreements. According to the Journal, the factors behind the elevated rates were related to a

scarcity of funds for banks, due to rising government deficits and the Fed's move to reduce its securities holdings in recent years.

CNN Business (9/17, Egan, 21.56M) reports on its website that "the NY Fed announced plans late Tuesday to hold another repurchase agreement operation on Wednesday that would aim to repurchase up to an additional \$75 billion." According to the article, "the episode demonstrates evidence of emerging strains in financial markets and raises concern that the Federal Reserve could be losing its grip on short-term rates." The article adds that "it's unclear what exactly is causing the stress in the overnight market, or how long it will last."

AFP (9/17) and Bloomberg (9/17, McCormick, Harris, 4.73M), among other news outlets, also cover the Fed's intervention.

Fed Likely To Lower Interest Rates On Wednesday With Economy Facing Risks. USA Today (9/17, Davidson, 10.31M) reports, "Despite firming inflation and easing trade tensions, the Federal Reserve is likely to lower interest rates Wednesday for the second time in less than two months and pave the way for another likely cut later this year to head off persistent risks from overseas." However, "with economic reports decidedly mixed in recent weeks, Fed Chairman Jerome Powell must bridge continued sharp divisions among Fed policymakers, many of whom favored no rate decrease in July." USA Today adds that "Powell also must endure continued taunts" from President Trump, "who has called for sharper rate cuts and even negative interest rates to help the US keep pace with Europe."

Manufacturing Production Rebounds.

Reuters (9/17, Mutikani) reports "US manufacturing output increased solidly in August, boosted by a surge in the production of machinery and other goods, but the outlook for factories remains weak amid rising headwinds from trade tensions and slowing global economies." The "fairly upbeat report from the Federal Reserve on Tuesday came as officials from the US central bank gathered for a two-day policy meeting." Reuters adds "manufacturing production rose 0.5% last month after an unrevised 0.4% drop in July, the Fed said. Economists polled by Reuters had forecast manufacturing output rising 0.2% in August."

Senators Urge Antitrust Regulators To Strenuously Investigate Big Tech.

The New York Times (9/17, McCabe, 18.61M) reports, "Senators pressed top antitrust regulators on Tuesday to aggressively investigate the power of the country's biggest tech companies, with some lawmakers questioning whether the officials had the will or resources to take on Silicon Valley's richest businesses." However, "the regulators – Joe Simons, the chairman of the trade commission, and Makan Delrahim, the top antitrust official at the Justice Department – offered few details about their inquiries into the industry," frustrating some lawmakers. Simons and Delrahim have "divided up responsibility for handling antitrust complaints about the companies," but "the accord between the agencies appears tenuous," and lawmakers also "pressed the regulators on Tuesday on reports that they were at odds over the investigations."

Trump Says US, Japan Have Reached A Trade Deal.

The Washington Post (9/17, 14.2M) reports that President Trump said Tuesday that he has "reached a trade deal with Japan but provided no details of its terms, including whether he had agreed to rule out imposing tariffs on Japanese automobiles." In a statement released by the White House, Trump said, "I am pleased to report that my Administration has reached an initial trade agreement regarding tariff barriers...with Japan and I intend to

enter into the agreement in the coming weeks.” The Post adds that Trump is “expected to meet” Japanese Prime Minister Shinzo Abe “later this month at the annual United Nations General Assembly session,” and White House officials “had been hopeful that they could announce major progress regarding the talks during the meeting.”

Administration Moves To Announce Trade Deals With Japan, India. The New York Times (9/17, Swanson, Dooley, Goel, 18.61M) reports that the Administration “is racing to announce limited trade deals with Japan and India before the end of the month, as President Trump tries to score some wins amid a trade fight with China.” The effort is “aimed at helping Mr. Trump overcome concerns about his trade approach before the 2020 election and prove to voters that he is delivering on a key promise to negotiate bilateral trade deals in America’s favor.” In addition, Trump “wants to calm the concerns of struggling farmers, who have been largely cut off from foreign markets like China in retaliation for the president’s trade war.”

Proposed Rules Would Give Greater Scrutiny To Foreign Investment In US Tech, Infrastructure, Data.


The Wall Street Journal (9/17, Ferek, Subscription Publication, 7.57M) reports the Administration on Tuesday released proposed rules that would subject foreign investors seeking to invest in US businesses involved in technology, infrastructure, and data to more stringent national security scrutiny.


The New York Times (9/17, Rappeport, 18.61M) says the new rules “would add teeth to a 2018 law, the Foreign Investment Risk Review Modernization Act, that expanded the powers of a government panel to block transactions on national security grounds.” They “would give the Committee on Foreign Investment in the United States, or CFIUS, greater power to stop foreign investment in areas the United States deems protected. While the rules would apply to any foreign investment, the effort is primarily aimed at preventing China from gaining access to sensitive American technology and other valuable assets.”

McConnell: Senate In “Holding Pattern” On Guns Until Trump Expresses Preferences.

The Washington Times (9/17, Sherfinski, 492K) reports Senate Majority Leader McConnell on Tuesday “said lawmakers are in a ‘holding pattern’ on gun-related legislation until President Trump clearly articulates what kind of package he would support.” McConnell “expressed an interest in acting in the wake of the recent shootings in Texas and Ohio, but reiterated that it will take support from the Democrat-controlled House, the Republican-controlled Senate, and Mr. Trump to get anything signed into law.” Said McConnell, “I know I’m the majority leader, but I’m telling you, I want to know what the President supports – it’s not unimportant to my members. ... Until we get that kind of guidance, we’re in a holding pattern, so to speak.”

Teens Arrested For Three High School Shooting Plots In California, Oklahoma.


NBC Nightly News  (9/17, story 6, 1:21, Holt, 5.96M) reported police in California and Oklahoma are “crediting tips in the public with possibly stopping school shootings in those states.” NBC’s Pete Williams said, “In southeastern Oklahoma, 18-year-old Alexis Wilson is charged tonight with making a terrorist threat, accused of telling a co-worker she wanted to shoot up McAlester High School, which she once attended.” He added, “In Desert Hot Springs, California, three 14-year-olds, two boys and a girl, are charged with threatening on social media to shoot their high school.”


On ABC World News Tonight  (9/17, story 2, 1:55, Muir, 6.62M), Steve Osunsami said that “a 16-year-old from Fresno high school in California” is also under arrest “after a post he made to Instagram.”

Some Of Trump’s Hurricane Briefings Do Not Include Meteorologists.


The Washington Post (9/17, Freedman, Samenow, 14.2M) reports that President Trump’s “inaccurate assertion” that Hurricane Dorian would impact Alabama “exposed a flaw in the White House’s storm briefing process – some of those meetings did not include meteorologists,” despite the fact that Trump “has an advantage compared to his predecessors: the presence of a highly qualified meteorologist on his White House staff. Kelvin Droegemeier, a longtime research meteorologist, serves as the head of the White House Office of Science and Technology Policy (OSTP).” But, Droegemeier “did not attend formal hurricane briefings provided to Trump in the run-up to Hurricane Dorian’s devastating strike in the northwest Bahamas and eventual landfall in North Carolina, according to a senior administration official.”

Tropical Storm Imelda Forms, Posing Risk Of Flash Floods In Texas, Louisiana.

The CBS Evening News  (9/17, lead story, 1:14, O'Donnell, 4.34M) reported “a tropical storm is hitting” Houston Tuesday night. Imelda “intensified rapidly, targeting the Houston area with life-threatening flash floods.”

On NBC Nightly News  (9/17, lead story, 0:55, Holt, 5.96M), Al Roker reported that “the flash flood watches extend into Louisiana.”

Hurricane Humberto Gaining Strength.

ABC World News Tonight  (9/17, lead story, 1:34, Muir, 6.62M) reported Hurricane Humberto is “gaining strength...with concern over dangerous rip currents.” ABC chief meteorologist Ginger Zee said Hurricane Humberto “should be a major hurricane by [Wednesday].”

DeVos Visits Nontraditional School In Cleveland.

The Cleveland Plain Dealer (9/17, Richardson, 895K) reports that “as part of her back to school tour of abstract learning facilities,” Education Secretary DeVos was in Cleveland Tuesday where she visited Edwins Leadership and Restaurant Institute, where “formerly incarcerated learn the ropes of fine dining and French cuisine.” DeVos said, “This is just a terrific example of the opportunity for education and serving in a way that some people gravitate to just like a duck to water. ... I have been tangentially involved in the restaurant business and I know that people who love to cook love to cook. When they find that passion and can develop that to the highest level of excellence, what could be better than that?” DeVos “did not say whether she thought there was a place for the federal government to assist a school like Edwins, though she listed making PELL grants or student loans available to entrants as a possible means for federal assistance.”

Trump Names Five Finalists For National Security Adviser Post.

Politico (9/17, Forgey, 4.29M) reports the President yesterday “revealed his top five candidates to replace former national security adviser John Bolton.” Politico adds that “speaking to reporters aboard Air Force One while en

route to California, Trump said he is considering Fred Fleitz, Lisa Gordon-Haggerty, Keith Kellogg, Robert O'Brien and Ricky Waddell to lead his White House's National Security Council." The New York Times (9/17, Baker, 18.61M) says that "in naming the five, Mr. Trump seemed to be ruling out several others who had been considered or proposed to him, including two top aides to" Secretary of State Pompeo – "Stephen E. Biegun, the special envoy for North Korea, and Brian H. Hook, the special envoy for Iran. Another who had been mentioned but was not included on the president's list was Richard Grenell, the ambassador to Germany and a conservative firebrand." The Washington Post (9/17, Gearan, 14.2M) reports "Grenell attended a dinner with Trump on Saturday amid speculation that he was in the running for Bolton's job," but "a senior administration official said...that Grenell was in Washington because he 'has been in discussions for weeks about another role the president wants him to play.'"

The New York Post (9/17, Moore, 4.57M) recounts "Trump praised Kellogg, saying 'he's been with me from the beginning. He's great,'" and "called O'Brien 'fantastic' and said he likes Waddell 'a lot.'" The Hill (9/17, Chalfant, 2.98M) reports "it's unclear when Trump will name his choice." Reuters (9/17, Mason), the Washington Examiner (9/17, Nelson, 448K), and the Daily Caller (9/17, 716K), among other news outlets, also report the story.

Senate Panel To Vote On Scalia Nomination September 24.

The Washington Examiner (9/17, Higgins, 448K) reports Senate Health, Education, Labor, and Pensions Chairman Lamar Alexander "announced Tuesday that the panel will vote on President Trump's pick to head the Labor Department, private sector lawyer Eugene Scalia, on Sept. 24, less than one week after his first nomination hearing." Scalia "has been criticized by Democrats and organized labor as too close to big business. The quick pace of the nomination and vote suggest the administration and its GOP allies don't want to give critics a chance to build up opposition to the nominee."

White House Fires DHS General Counsel.

The New York Times (9/17, Kanno-Youngs, Haberman, 18.61M) reports, "The White House on Tuesday fired John Mitnick, the general counsel for the Department of Homeland Security, after months of shake-up at an agency responsible for carrying out President Trump's immigration agenda." An Administration official "said Tuesday evening that Chad Mizelle, an associate counsel to the president, would replace Mr. Mitnick." However, "a Department of Homeland Security official said later that Joseph B. Maher, the department's principal deputy general counsel, would be taking over."

Administration Proposes New Rules To Streamline Disciplinary Process For Federal Employees.

The Washington Post (9/17, Yoder, 14.2M) reports federal agencies would have more latitude "in disciplining their employees, and the employees would be guaranteed only the minimum protections required by law, under rules the Trump administration proposed Tuesday." The rules would discard "many of the practices agencies have followed in disciplining employees while urging them to move as fast as the law allows." According to the article, "most of the changes would put in place the parts of a May 2018 executive order from President Trump that are not affected by a court injunction blocking portions of that order and two others issued at the same time."



Media Analyses: Lewandowski Testimony Enrages Democrats.

Media reports and analyses, including segments on all three network newscasts, cast Democrats on the House Judiciary Committee as infuriated by the testimony of Corey Lewandowski. Politico (9/17, Desiderio, Cheney, 4.29M) says, for example, that Lewandowski “sent Democrats into a rage...as he swatted down dozens of questions about potential obstruction of justice by the president.” Politico adds that “two White House lawyers were seated behind an indignant Lewandowski as he repeatedly deferred to their demands to sharply restrict his testimony.” The AP (9/17, Jalonick) reports Lewandowski, moreover, “made clear his dislike for the House majority in the opening statement, calling them petty and asserting that investigations of the president were conducted by ‘Trump haters.’”

The Daily Caller (9/17, 716K) quotes from Lewandowski’s opening statement: “In conclusion, and it’s sad to say, this country has spent over three years and 40 million taxpayer dollars on these investigations, and it’s now clear that the investigation was populated by many Trump haters who had their own agenda – to take down a duly elected president of the United States.” USA Today (9/17, Jansen, 10.31M) reports Lewandowski also “said...that it was ‘very unfair’ that committee Democrats unilaterally changed the rules a week ago to make the hearing part of an impeachment proceeding.” Said Lewandowski, “We as a nation would be better served if elected officials like you concentrated your efforts to combat the true crises facing our country as opposed to going down rabbit holes like this hearing.” President Trump wrote on Twitter, “Such a beautiful Opening Statement by Corey Lewandowski! Thank you Corey!”

Fox News (9/17, Pappas, 27.59M) recounts on its website that Lewandowski “declined to play along with certain questions.” Rep. Hakeem Jeffries (D-NY), for example, “asked Lewandowski if he was Trump’s ‘hitman, the bag man, the lookout, or all of the above?’” Lewandowski replied, “I think I’m the good looking man, actually.” The New York Post (9/17, Schwab, 4.57M) reports, meanwhile, that at one point, Chairman Jerrold Nadler “said Lewandowski could go ahead and answer a question” from Rep. Sheila Jackson-Lee (D-TX) “even though her time had elapsed.” Said Lewandowski, “I don’t believe there was a question, Congressman. ... Just a rant.” Lewandowski also “poked fun at” Rep. Eric Swalwell (D-CA) – “who already dropped out of the 2020 race – by calling him ‘President Swalwell.’” The San Francisco Chronicle (9/17, Ting, 2.67M) indicates that Swalwell “tried to make Lewandowski read his own notes he submitted to special counsel Robert Mueller regarding a meeting with...Trump on July 19, 2017.” Lewandowski “refused to read it,” and said, “President Swalwell, I’m very happy with what I’ve written but you’re welcome to read it if you like.”

Writing for the CNN (9/17, 83.16M) website, Chris Cillizza said that “within the first five minutes of...Lewandowski’s ‘testimony’...it became crystal clear what...Trump’s former campaign manager was up to:

trolling to please his old boss.” Kaitlan Collins similarly said on CNN’s Situation Room  (9/17, 734K) that Lewandowski “was performing for an audience of one.” Trump, and Gloria Borger said on CNN’s Situation Room  (9/17, 734K) that Lewandowski “did what he wanted to do, which was to look like he was stonewalling Congress, to play to the President – and to play to people who might one day get the chance to vote for him in the state of New Hampshire.” Under the headline “Corey Lewandowski Debuts His Senate Campaign Theme: Unbridled Nastiness,” meanwhile, Dana Milbank writes in the Washington Post (9/17, 14.2M) that Lewandowski’s “combative performance brought the House Judiciary Committee, never a harmonious assembly, to a new level

of acrimony. ... Back and forth lawmakers and witness went: Coverup. Socialists. Obstruction. Lie. Contempt. Fake news. Impeachment. Joe Biden's record player. Trump's Sharpie."

The Washington Post (9/17, 14.2M) says "it was Lewandowski's attitude that most infuriated panel Democrats – even prompting a contempt threat" from Rep. David Cicilline (D-RI). The Post reports that "time after time, Lewandowski tried to show that this was his performance and he was the man in control, even tweeting from the room about his possible 2020 bid for the Senate and lecturing a congressman for saying the tooth fairy wasn't real. 'New website just launched to help a potential senate run. Sign up now!' he wrote during a panel break, a reference to his potential challenge" to Sen. Jeanne Shaheen (D-NH). NBC Nightly News (9/17, story 7, 0:30, Holt, 5.96M), the CBS Evening News (9/17, story 8, 1:35, O'Donnell, 4.34M), and ABC World News Tonight (9/17, story 6, 1:35, Muir, 6.62M) all referred to "fireworks" on Capitol Hill, and ABC also reported that "during a break from the hearing, Lewandowski took time to promote a PAC, encouraging him to make a possible Senate run in New Hampshire."

NPR (9/17, Ewing, 3.12M) reports "Democrats were frustrated at what they called stonewalling," while "Republicans were angry about what they called a waste of time." Reuters (9/17, Morgan, Wolfe) says Lewandowski, "vigorously defended his former boss and lashed out at Democrats but repeatedly dodged their questions during a contentious hearing before a...panel considering whether to impeach Trump." The AP (9/17) indicates he did "confirm" that Trump "asked him to urge Jeff Sessions to reverse himself and oversee the Russia investigation." Lewandowski said he "never delivered that message, but he told the House Judiciary Committee that Trump didn't ask him to break the law." The AP reports that when "asked why, according to the Mueller report, he never delivered the message to Sessions as instructed, Lewandowski answered that he had taken his kids to the beach." The New York Times (9/17, Haberman, Fandos, 18.61M) covers Lewandowski's appearance under the headline "Lewandowski Confirms Trump Asked Him To Help Curtail Mueller Inquiry," while the Washington Times (9/17, Mordock, 492K) titles its story "Corey Lewandowski Hearing Erupts In Chaos Over Mueller Report." The Los Angeles Times (9/17, Megerian, 4.64M), Bloomberg (9/17, House, 4.73M), The Hill (9/17, Beavers, 2.98M), CQ Roll Call (9/17, Ruger, 154K) and the Wall Street Journal (9/17, Ballhaus, Hughes, Subscription Publication, 7.57M), among other news outlets, also report the story.

Lewandowski said on Fox News' The Story (9/17), "I think I reiterated what the American people already knew: There was no collusion and obstruction. The Mueller report was very clear about that. And what we know, the far left wing of the Democratic party has to have these hearings to protect themselves in their congressional districts from further-left progressives who want to take them out in their primary races. This is all politics, and the truth is it's a disservice to the American people." Lewandowski added, "I've spent more than 20, maybe 25 hours, answering questions before the House Intelligence Committee, the Senate Intelligence Committee, the Special Counsel's office. I have nothing to hide, because we never committed any crimes in the campaign. We never colluded with anyone, which is exactly what the Mueller report says."

House Judiciary Committee ranking member Rep. Doug Collins (R-GA) said on Fox News' The Story (9/17) that Nadler "has turned this into a press release committee. All they want to do is have cameras show up, the press show up, and they will throw anything they can at the President to try to tear him down. Anything to try and tear him down. They have become literally the political arm of the DCCC."

Rep. Jackie Speier (D-CA) said CNN's The Lead (9/17, 649K), "I think you have to look at Mr. Lewandowski as an adverse witness. He had no interest in complying with this actual subpoena outside of showing up. He intended to obstruct justice once again, frankly, by not being willing to give answers to questions by the Democrats. I think if I were Mr. Nadler right now, I would be slapping Mr. Lewandowski with an inherent contempt order and calling him in front of the House of Representatives and fining him."

Rep. Steve Cohen (D-TN) said on CNN's Situation Room (9/17, 673K), "I think we could hold him in contempt of Congress for refusal to answer questions. I don't know that we will. I think we should and I think we should have done it before. I suggested it months and months and months ago that we should have done it with Attorney General Barr for refusing to show up and others. We need to get tougher because the Republicans play tough" because "they know that there is information to be gained from seeing information in the grand jury testimony and from documents that we have subpoenaed and witnesses we have subpoenaed and they're trying to stop it as much as they can. Trump knows what's in there, and Trump is scared to death of the truth coming out."

Media Analyses: Lewandowski May Ride House Hearing Performance Into NH Senate Race.

The Washington Times (9/17, McLaughlin, 492K) reports Lewandowski, who is considering a Republican bid to unseat Shaheen, "has been consuming most of the oxygen in the" GOP primary – "and he's not even a candidate yet." The Times says that Lewandowski's "loyalty to Mr. Trump has earned him a rarefied status among the president's followers and given him a national profile that analysis say could excite voters and help him rake in tons of money" if he runs. The Times adds, "During a break in his contentious hearing before the House Judiciary Committee, Mr. Lewandowski tweeted out the link to a new website aimed at boosting his Senate hopes. It prominently features a Mr. Trump quote praising Mr. Lewandowski. Michael Dennehy, a New Hampshire-based Republican strategist, said Mr. Lewandowski 'truly is a mini-me of Donald Trump.'"

CQ Roll Call (9/17, Connolly, 154K) reports, "Frustrating the Democrats and proving loyalty to...Trump: That's just good politics for a Republican." CQ Roll Call says Lewandowski seemed "to be banking on [that] Tuesday as he testified before the House Judiciary Committee and continued to tease a possible bid for Senate. ... Not only did fellow Republicans give him ample opportunities to praise" Trump, but Lewandowski also "used Twitter to pique interest in the hearing before it started, and during a break sent out a link to a potential campaign website." CQ Roll Call adds that with three other candidates already in the GOP Senate primary, "Trump's base could be the key to coming out first in that crowd." Said Dennehy, "Whoever is more closely aligned to Trump will win the primary. If Trump endorses Lewandowski – it's game over and Corey wins in a landslide."

The Hill (9/17, Greenwood, 2.98M) quotes Lewandowski as tweeting during a break in yesterday's hearing, "New website just launched to help a potential senate run. Sign up now!" The Daily Beast (9/17, Brodey, Trudo, 1.39M) reports that "Tuesday's high-profile hearing was essentially a coming-out party for Lewandowski's long-teased, but still unannounced campaign for US Senate in New Hampshire: he talked up his 'blue collar' roots and service to...Trump while effusively praising his former boss and gleefully trolling his Democratic questioners."

NYTimes Decries Democrats' Conflicting Messages On Impeachment.

In an editorial, the New York Times (9/17, 18.61M) says that while the House Judiciary Committee "has begun an inquiry to determine whether to recommend the impeachment of President Trump," there is "tremendous

confusion about what the Judiciary Committee is up to – largely because of conflicting signals from House Democrats.” House Speaker Pelosi “paint[s] the committee’s work as garden-variety oversight,” and “as a result, even Democratic lawmakers don’t seem to know whether they are engaged in an impeachment inquiry.” The Times says the “contradictory statements make Democrats look divided and conflicted, complicating efforts to build public confidence in their oversight powers,” and calls on Democrat leaders to “try to find a way forward that, at the very least, doesn’t leave members contradicting one another and further embolden Mr. Trump.”

DOJ IG’s Findings Are Driving Force Behind Possible Criminal Charges For McCabe.

The Washington Times (9/17, A1, Scarborough, 492K) reports that Justice Department Inspector General Michael Horowitz’s report “is the driving force for possible criminal charges against former FBI Deputy Director Andrew McCabe, as his attorneys and the department square off in a legal and media showdown.” The IG found that McCabe “lied to fellow agents and cast blame on colleagues for his orchestrated press leak.” McCabe “rejects the inspector general’s conclusions,” and he “filed suit last month in US District Court alleging that the Trump Justice Department illegally fired him in retaliation for pursuing the Russia investigation.” The Times story goes on to detail Horowitz’s conclusions “that resulted in [McCabe’s] firing in March 2018, a few days short of full retirement, and prompted US Attorney Jessie K. Liu to weigh criminal charges.”

Comey Says He Is “Highly Confident” He Won’t Be Indicted.

The Washington Examiner (9/17, Dunleavy, 448K) reports that former FBI Director James Comey said Monday that he does not think he will be indicted. At an appearance with “Josh Campbell, his former special assistant at the FBI and now a CNN legal analyst, to discuss Campbell’s new book Crossfire Hurricane at George Washington University,” Comey said, “I keep seeing that I’m going to be indicted, which they said over and over again for the last two years. I’m highly confident that’s not true. So then they’ll just move on, making other stuff up after that peters out.”

Schiff: Acting DNI Has Refused To Hand Over Whistleblower Complaint.

The Washington Post (9/17, Demirjian, 14.2M) reports Acting DNI Joseph Maguire will “not comply with a House Intelligence Committee subpoena ordering him to provide the panel with a whistleblower’s report of ‘serious misconduct,’ escalating a standoff with the panel’s chairman over a complaint he believes could involve the White House.” House Intelligence Chairman Adam Schiff said, “We’re determined to make sure that the whistleblower is able to provide his complaint to Congress, or her complaint to Congress, and that this urgent matter is addressed. [Maguire] has yet to provide the complaint in response to the Committee’s subpoena, so I expect him to appear on Thursday, under subpoena if necessary.”

Politico (9/17, Cheney, 4.29M) reports Schiff “warned the agency might be acting to conceal high-level wrongdoing by President Donald Trump or his immediate advisers.” However, DNI general counsel Jason Klitenic “insisted in a letter to Schiff on Tuesday that Maguire had followed the letter of the law in blocking the transmission of the complaint to Congress.” Klitenic also called it “premature” for Maguire to appear on Thursday before Congress, “saying Maguire wouldn’t be available on short notice and that he’s still considering the appropriate response to the committee’s demands.”


The New York Times (9/17, Barnes, Fandos, 18.61M) reports, "Still, a senior intelligence official said, Mr. Maguire wants to find a way to work with the committee and try to accommodate Mr. Schiff's requests while still ensuring the whistle-blower's identity is protected."

Blasey Ford Friend Says She Doubts Her Accusation Against Kavanaugh.

Breitbart (9/17, Furr, 673K) reports that according to a new book written by New York Times reporters Robin Pogrebin and Kate Kelly, titled "The Education of Brett Kavanaugh: An Investigation," Leland Keyser, a friend of Christine Blasey Ford, who claims she was sexually assaulted by Supreme Court Justice Brett Kavanaugh in 1982, said the story of the alleged assault "didn't make any sense" and that "she was threatened with a smear campaign if she did not support it." CBS' Jan Crawford reported Monday that Keyser claimed "Ford's allies pressured her" to support Ford's accusation and that she was threatened with a "smear campaign" if she did not. Crawford tweeted Monday night, "We report tonight the real bombshell: Christine Ford's close HS friend (who Ford says was at the party when Kavanaugh allegedly assaulted her) said Ford's story is not believable and told the FBI Ford's allies pressured her, threatened her with a smear campaign to say otherwise" The New York Post (9/17, Moore, 4.57M) also reports on Keyser's comments.

Pence: Calls For Kavanaugh's Impeachment Are A "Disgrace." The Federalist (9/17, Justice, 126K) reports Vice President Pence said that calls from Democratic presidential candidates for Kavanaugh to be impeached are a "disgrace." In remarks at the Heritage Foundation, Pence said, "The Democrats and their allies in the media are obviously getting desperate. ... This week, they've taken to smearing a sitting justice on the Supreme Court of the United States with discredited allegations. The calls by Democratic candidates for the president to remove Justice Kavanaugh from the court are a disgrace and nothing short of an attack on our independent judiciary." Pence continued, "Justice Brett Kavanaugh is a good and decent man. ... He is a principled jurist and a credit to the highest court in the land, and these attacks on Justice Kavanaugh must stop."

Senate Judiciary Chairman Lindsey Graham said on Fox News' Hannity (9/17, 535K), "It is not really news that the New York Times did a sloppy job reporting about Trump and Kavanaugh because they are so biased, but what is news to me is that two United States Senators running for president have called for Kavanaugh's impeachment based on an article in the New York Times that is bogus. And a member of the house has introduced impeachment resolution of Judge Kavanaugh based on an erroneous, scurrilous New York Times story. So here is what I want you to know, any impeachment of Judge Kavanaugh based on the New York Times story is dead on arrival in the Senate. Any impeachment of President Trump based on the Mueller report is dead on arrival in the United States Senate."

NYTimes Reporters Say Editors Removed Key Information From Kavanaugh Story. Politico (9/17, Calderone, 4.29M) reports that Pogrebin and Kelly, who revealed the new allegation against Kavanaugh "blamed [the New York Times'] editors for a critical piece of information not appearing in their original story." In an interview with MSNBC's Last Word  "they said...that they wrote in the draft of their Sunday Review piece that a woman who Kavanaugh was said to have exposed himself to while a student at Yale had told others she had no recollection of the alleged incident," but their editors "removed the reference." Said Pogrebin, "It was just sort of...in the haste of the editing process."

The Washington Free Beacon (9/17, Piro, 78K) reports that on ABC's The View, Pogrebin "said the controversial initial tweet promoting" the story was a "misworded tweet" and "that she did not intend for it to be published." Pogrebin "excused the tweet...by saying reporters are asked to draft tweets to go with their articles." She said the draft tweets "don't always get used, they don't always get sent out, they often don't."

Trump: NYTimes Has Become A "Sad Joke" Around The World. In a tweet Tuesday morning, President Trump called the Times a "journalistic disaster" that "has become a sad joke" around the world. Trump wrote, "The New York Times is at its lowest point in its long and storied history. Not only is it losing a lot of money, but it is a journalistic disaster, being laughed at even in the most liberal of enclaves. It has become a very sad joke all over the World. Witch Hunt hurt them... That story (Kavanaugh) is nowhere near the standard that should be met in publishing a story.' @brithume @FoxNews"

Tuesday evening, Trump tweeted, "The New York Times is now blaming an editor for the horrible mistake they made in trying to destroy or influence Justice Brett Kavanaugh. It wasn't the editor, the Times knew everything. They are sick and desperate, losing in so many ways!"

Trump's tweet Tuesday morning referred to comments by Brit Hume on Fox News Special Report (9/16, 1.53M) Monday evening. Hume made a similar argument on Fox News' Tucker Carlson Tonight (9/17) Tuesday evening. Hume said, "This is a story that should never have gotten anywhere near print. This is nowhere near publishable. It's not even remotely close."

The Washington Examiner (9/17, Ferrechio, 448K) reports that Senate Majority Leader McConnell "condemned the decrease in journalistic standards" following the Times story. During a briefing with reporters, McConnell said, "I'm distressed about the declining journalistic principles so much on display across all of the world of journalism, up to and including of all publications, the New York Times. ... It's a very distressing development." McConnell said the Times "ought to be embarrassed."

Pressley Introduces Impeachment Resolution Against Kavanaugh. USA Today (9/17, Wu, 10.31M) reports that in the wake of the Times report, Rep. Ayanna Pressley (D-MA) has introduced an impeachment resolution against Kavanaugh. In a statement to Boston public radio station WBUR, Pressley said, "I believe Christine Blasey Ford. I believe Deborah Ramirez. It is our responsibility to collectively affirm the dignity and humanity of survivors. ... Sexual predators do not deserve a seat on the nation's highest court, and Brett Kavanaugh's confirmation process set a dangerous precedent. ... We must demand justice for survivors and hold Kavanaugh accountable for his actions." USA Today adds that Pressley's resolution "is unlikely to go anywhere" because "Democratic leadership seems to have little appetite for a fight over impeachment."

Harris Calls On House Judiciary Committee To Investigate Kavanaugh. Reuters (9/17, Becker) reports Sen. Kamala Harris (D-CA) on Tuesday urged the House Judiciary Committee to investigate Kavanaugh in light of the new allegations. In a letter to Chairman Jerrold Nadler, Harris, who has called for Kavanaugh's impeachment, said the panel "hold Mr. Kavanaugh accountable for his prior conduct and testimony."

Gorsuch Says He Opposes "Nine Older People Sitting In Washington Making Stuff Up."

The Washington Examiner (9/17, Quinn, 448K) reports that Supreme Court Justice Neil Gorsuch "is firing back at the critics of his judicial philosophy," including some of his brethren on the High Court, "who believe the Constitution should be interpreted differently in the modern era." Gorsuch "has positioned himself as a bulwark against" what he describes as "nine older people sitting in Washington making stuff up." Said Gorsuch, "When

that happens, your rights get diminished and the Constitution gets amended in ways you never agreed to." The Examiner adds that while Gorsuch did not mention President Trump, "he did make an impassioned plea for 'civility' that could be seen by some as a veiled shot at Trump, who even his supporters would concede adopts a brutish coarseness, often via Twitter, to communicate."

New York Judge Steps Down After Posting Trump Slogan With An Image Of A Noose.

The New York Times (9/17, Otterman, 18.61M) reports that six weeks after Kyle Canning he became a judge in Altona, New York in January 2018, "he posted an image of a noose in front of a black background on his Facebook page." The post, which read, "IF WE WANT TO MAKE AMERICA GREAT AGAIN WE WILL HAVE TO MAKE EVIL PEOPLE FEAR PUNISHMENT AGAIN," was "brought to the attention of the state Commission on Judicial Conduct." After an investigation was opened, Canning "stepped down." While Canning's post included President Trump's campaign slogan, Canning, who is not a lawyer, "said he did not read it that way when he publicly shared it to his Facebook page." He "said he thought the post was supporting the death penalty, and he did not consider its racial connotations." Said Canning, "There is not a man that I could despise more than Donald Trump."

Sinema Faces Arizona "Censure" For Voting To Confirm Trump Nominees.

The Washington Examiner (9/17, Brown, 448K) reports that Sen. Kyrsten Sinema (D-AZ) "is facing possible censure from the liberal caucus" of the Arizona Democratic Party for "failing to support the tenets of the 2016 Democratic Party Platform." A censure resolution from the caucus which will be considered at the party's quarterly meeting on Saturday, "delineate[s] the reasons why Sinema has, in the estimation of the caucus, failed to live up to those tenets when she voted to confirm" Attorney General Barr and Interior Secretary Bernhardt, "as well as neglecting to co-sponsor legislation that would reinstate net neutrality rules."

Cook To Leave Congress, Plans To Run For County Supervisor.

The Palm Springs (CA) Desert Sun (9/17, Metz, 131K) reports Rep. Paul Cook (R-CA) "announced his intention to retire...after completing his fourth term in January 2021 in order to run for San Bernardino County District 1 Supervisor." Cook "was first elected in 2012 after serving six years in the California State Assembly," and "joins 11 other Republican members of Congress who've announced they won't be seeking reelection." Cook is, says the Los Angeles Times (9/17, Mai-Duc, 4.64M), "the first to announce his retirement in California's Republican US House delegation, which has been greatly diminished in recent years," as "in the 2018 midterms, Democrats took control of half of the 14 remaining Republican seats in California, which has a total of 53 congressional districts."

The Hill (9/17, Rodrigo, Brufke, 2.98M) reports "President Trump won Cook's district by more than 15 points in 2016," and "Cook won his last election there against another Republican with 60 percent of the vote." Politico (9/17, Zanona, White, 4.29M) indicates Cook "was backed by Trump in his race last year against former Assemblyman Tim Donnelly, a Tea Party favorite" and co-founder of an anti-immigration group "that monitors the border." The CNN (9/17, Byrd, 83.16M) website calls CA8 "safely Republican."

The AP (9/17, Beam) reports that in a statement, "Cook hinted at frustrations with the bureaucracy in Washington." The San Bernardino (CA) Sun (9/17, Emerson, 129K) quotes him as saying, "After twenty-six years in the Marine Corps, my attention turned first to local government," and "while I've been called to serve in other

capacities such as Congress, my focus has always been on empowering communities and making sure local residents have the strongest voice in decisions that affect them."

DOJ Lawsuit Seeks All Proceeds From Snowden's Memoir.

The AP (9/17, Balsamo) reports that Justice Department has filed a lawsuit against former National Security Agency contractor Edward Snowden, "alleging he violated nondisclosure agreements by publishing a memoir without giving the government an opportunity to review it first." DOJ is "seeking to 'recover all proceeds' from Snowden's book, which was released Tuesday."

The New York Times (9/17, Savage, 18.61M) reports in the lawsuit, the DOJ "complained that by publishing the book, Mr. Snowden violated his legal obligation to let censors at the C.I.A. and the N.S.A. vet the manuscript first, and so he had to forfeit any profits." However, Ben Wizner, an American Civil Liberties Union lawyer who represents Snowden, "said that the book contained no classified information that the news media had not previously published."

The Washington Post (9/17, 14.2M), Reuters (9/17), and Bloomberg (9/17, Larson, 4.73M) also cover the lawsuit.

Conservative Groups Urge Administration To Weaken Standards For Home Appliances.

The New York Times (9/17, Tabuchi, 18.61M) reports on "a broad campaign coordinated by conservative organizations with ties to fossil-fuel companies," aimed at persuading the Trump Administration "to weaken standards on a long list of home appliances." The Times story focuses on what it describes as "the dishwasher lobby." It cites an online petition from FreedomWorks that reads, "Dishwashers used to clean a full load of filthy dishes in under an hour. But now they take an average of two and a half hours and STILL leave dishes dirty!" This site attributes this decline to "crazy environmentalist rules." The Times also reports that the dishwasher effort is "one of many cases where a Trump administration regulatory rollback is in fact opposed by the very industry the White House claims it will help." Jennifer Cleary of the Association of Home Appliance Manufacturers wrote in a 2018 letter to Administration officials that weakening the standards would mean "additional costs for manufacturers and, ultimately, consumers."

Army Experiments With New Recruiting Tactics.

The Wall Street Journal (9/17, Kesling, Subscription Publication, 7.57M) reports that the US Army last year recruited just under 70,000 troops, which was about 10 percent less than its goal. Now, in a pilot program in Chicago, the Army is trying new recruiting tactics which use market data to adjust its message by neighborhood and conform its advertising and staffing to the demographics of the area.

Car Crashes Into Lobby Of Trump Tower In New Rochelle.

The New York Post (9/17, Musumeci, 4.57M) reports, "A car plowed into the lobby of Trump Plaza in New Rochelle Tuesday night." video posted on social media "shows a banged-up black Mercedes-Benz sitting inside the marble lobby of the 40-story luxury residential building." CBS New York reporter Tony Aiello tweeted, "Workers at Trump Plaza New Rochelle say after car plowed into lobby, make [sic] driver got out and took a seat on a sofa. Said nothing. Several injuries but none are life threatening." The New York Times (9/17, Zaveri, Padilla, 18.61M) says that while police were still investigating, the crash "did not appear to be intentional, said

Sgt. Chris Castiglia of the New Rochelle Police Department.” The Washington Times (9/17, Morton, 492K) also reports on the crash.

Veteran Journalist Cokie Roberts Dies.

All three network news broadcasts reported on the death of journalist Cokie Roberts, who died Tuesday of complications from breast cancer. The CBS Evening News (9/17, story 12, 1:41, O'Donnell, 4.34M) reported Roberts, whose parents were both members of Congress from Louisiana, was “a best selling author, correspondent, political analyst, and anchor.” On NBC Nightly News (9/17, story 9, 1:43, 5.96M), Lester Holt called Roberts “one of the best in our business.” David Muir said on ABC World News Tonight (9/17, story 7, 4:18, 6.62M) that Roberts “had a brilliant mind, matched only by her kindness, her grace and, of course, her wit.”

USA Today (9/17, Behrmann, 10.31M) reports that President Trump commented on Roberts’ passing by calling her a “professional,” but adding that she “never treated me nicely.” Speaking to reporters aboard Air Force One, Trump said, “I never met her. She never treated me nicely. But I would like to wish her family well. She was a professional, and I respect professionals. I respect you guys a lot, you people a lot. She was a real professional. Never treated me well, but I certainly respect her as a professional.”

RNC Raised “Record-Setting” \$23.5M In August.

In an exclusive, Fox News (9/17, Re, 27.59M) reports in an online article that the RNC “is expected to announce this week that it raised a record-setting \$23.5 million in August and had \$53.8 million cash on hand as of the end of that month – signaling growing GOP momentum heading into the 2020 elections.” The group’s “August fundraising total was the highest recorded in August during an off-cycle year by either the RNC or DNC, and the RNC has not had as much cash on hand since September 2016, just before Election Day. The RNC’s figures included only money directly contributed to the committee and did not include money contributed to any other joint committee.”

Trump Camp Severs Ties With Key Florida Adviser At DeSantis’ Urging.

Politico (9/17, Isenstadt, Dixon, 4.29M) reports that President Trump’s campaign “has severed ties with Florida adviser Susie Wiles, leaving the president without a top adviser in a major battleground state going into the 2020 election. The move was made at the urging of Florida Gov. Ron DeSantis, who has been attempting to install his own allies in the state party.” Politico says Wiles’ exit “followed weeks of behind-the-scenes drama that has prompted turnover at the highest levels of the state GOP apparatus. DeSantis personally made it clear he wanted Wiles out, according to two senior Republicans familiar with discussions between DeSantis and the Trump campaign.”

Businessman In North Macedonia “Hijacked” Facebook Page “Vets For Trump.”

The Washington Post (9/17, Timberg, 14.2M) reports, “The Facebook page ‘Vets for Trump’ was for most of its existence exactly what it seemed: a place where former US service members touted Donald Trump, discussed veterans issues and shared conservative memes with its more than 100,000 followers. Then in March, say its

longtime operators, a North Macedonian businessman hijacked it, leaving the Americans to watch helplessly as their page began operating under foreign control. Their messages seeking help from Facebook led to months of miscommunication and inaction.” The incident, says the Post, “underscores how money, politics and online misinformation remain deeply and often invisibly entangled ahead of the 2020 presidential election, despite years of promises by government officials and technology companies to combat such problems.”

WSJournal: GOP Leaders Shouldn't Cancel Presidential Primaries.

In an editorial, the Wall Street Journal (9/17, Subscription Publication, 7.57M) urges Republican Party leaders not to cancel presidential primaries in their states. The Journal argues that the three Republicans currently seeking to challenge President Trump, while long-shots, are serious candidates that could make compelling policy proposals that deserve to be heard.

NBC/WSJournal Poll: Biden 31%; Warren 25%; Sanders 14%; Buttigieg 7%; Harris 5%.

On its website, NBC News (9/17, Murray, 6.14M) reports that a national NBC News/Wall Street Journal poll of 506 Democratic primary voters, taken Sept. 13-16, shows ex-Vice President Joe Biden leading the race for the 2020 Democratic presidential nomination with 31%, followed by Sen. Elizabeth Warren (D-MA) at 25%, Sen. Bernie Sanders (I-VT) at 14%, South Bend Mayor Pete Buttigieg at 7%, and Sen. Kamala Harris (D-CA) at 5%; no other contender topped 4%. In a similar poll taken in July, Biden led with 26%, followed by Warren at 19%, and Harris and Sanders each at 13%. The Wall Street Journal (9/17, Thomas, Subscription Publication, 7.57M) reports that the poll was conducted in the wake of last week's Democratic presidential debate.

On its website, CNBC (9/17, Harwood, 3.62M) reports that Biden “commands 49% among African-Americans, 46% among senior citizens, and 42% among moderate and conservative Democrats.” Warren, meanwhile, “leads Biden by roughly two-to-one among liberals and Democrats under 35, breaks even among whites, and holds a double-digit edge among those seeking large-scale change in the post-Trump era.” In addition, “Warren now holds a clear edge in enthusiasm. Fully 70% of” those polled “describe themselves as enthusiastic or comfortable about her candidacy, more than for either Biden or Sanders. As a result, 45% of Democratic primary voters call Warren either their first or second choice. That compares to 41% for Biden, 29% for Sanders, 19% for...Buttigieg and 14% for...Harris.”

California Poll: Biden 26%; Sanders 26%; Warren 20%; Yang 7%; Harris 6%; O'Rourke 5%.

An Emerson College poll of 424 California Democratic voters, taken Sept. 13-16, shows Biden and Sanders tied for the lead with 26% each, followed by Warren at 20%, entrepreneur Andrew Yang at 7%, Harris at 6%, and ex-Rep. Beto O'Rourke (D-TX) at 5%; no other contender tops 4%. The Hill (9/17, Greenwood, 2.98M) reports, “The survey is a sign that Harris may face a difficult battle in her home state's nominating contest, a delegate-rich election that carries more significance than ever because of an accelerated primary schedule that places it on Super Tuesday, when voters in a dozen states will cast their ballots for the Democratic nomination. ‘Senator Kamala Harris is in trouble in her home state. If she is unable to gain momentum in Iowa or New Hampshire, come Super Tuesday she might have a similar fate to Sen. Marco Rubio in 2016, when he was unable to win his home state of Florida and dropped out of the race,’ Emerson Polling Director Spencer Kimball said.”

New York Poll: Biden 22%; Warren 17%; Sanders 15%. The New York Post (9/17, Campanile, 4.57M) reports that a Siena College poll of 359 New York Democratic voters, taken Sept. 8-12, shows Biden leading with 22%, followed by Warren at 17%, and Sanders at 15%; no other candidate topped 4%. In a separate

article, the New York Post (9/17, Campanile, 4.57M) reports that New York City Mayor Bill de Blasio “is registered as having ‘0’ support from Big Apple Democrats in” in the survey.

Trump Camp Out With Video Targeting Biden On Gaffes.

USA Today (9/17, Santucci, 10.31M) reports that President Trump’s campaign takes aim at former Vice President Joe Biden’s “frequent slip-ups in a new video released Tuesday.” Trump campaign manager Brad Parscale “tweeted the video, which strings together clips of Biden’s verbal gaffes and political commentators questioning his ability to lead the nation. The video shows Biden mixing up his words, confusing which state he was speaking in and on more than one occasion accidentally referring to fellow primary candidates as ‘the president.’”

In an online article, Fox News (9/17, Steinhauer, 27.59M) reports that the video “stitches together everything from [Biden’s] recent debate-stage musing about ‘record players’ to his statement that ‘poor kids’ are just as talented as ‘white kids.’ Interspersed with the clips of the 76-year-old Biden’s comments are those of pundits wondering about his stumbles, shakiness, mental and physical stamina, whether he’s ‘lost a step’ and whether he’s ‘equipped for a very grueling campaign.’” The Hill (9/17, Coleman, 2.98M) reports that the video includes a clip of Sen. Cory Booker (D-NJ) “saying in an interview, ‘There are definitely moments where you listen to Joe Biden and you just wonder.’ The video ends with Biden sitting amongst an audience, with his eyes closed and seemingly asleep.”

Reuters Analysis: Biden’s Leftward Shift On Environment May Hurt Him In Rust Belt. Under the headline “Biden’s Bid To Attract Rust Belt Workers Faces Troubles In His Own Backyard,” Reuters (9/17, Renshaw) reports that over “a dozen current and former union leaders and workers who spoke to Reuters recently in Philadelphia, questioned” Biden’s “loyalty.” Reuters reports that the union leaders say that “in embracing calls to phase out the fossil fuel industry that many of the region’s pipefitters and steelworkers rely on for jobs,” Biden “risks losing his ‘hard-hat’ appeal in a critical swing state. ‘I think Biden has taken our votes for granted. Our plant closed and we didn’t hear from him,’ said Ryan O’Callaghan, the former union head of a now-shuttered Philadelphia refinery.” Reuters says Biden’s “silence on the refinery...suggests how the party’s aggressive environmental agenda may be boxing Biden out of an issue that seemingly plays into his brand of politics.”

WSJournal Analysis: Biden Walking Tightrope On Economic Policy. Under the headline “‘Nobody Has To Be Punished’: Joe Biden’s Economic Tap Dance,” the Wall Street Journal (9/17, Schlesinger, Thomas, Subscription Publication, 7.57M) reports that on economic policy, Biden is walking a tightrope, offering plans that he hopes will appeal to the activist left but also won’t turn off moderates. The Journal says that as Sens. Bernie Sanders (I-VT) and Elizabeth Warren (D-MA) push far-left plans on taxes and business regulation, Biden is setting more moderate goals with his proposals on the same topics.

Trump Downplays Size Of Warren’s NYC Crowd.

CQ Roll Call (9/17, Bennett, 154K) reports that President Trump, “who often touts the size of crowds at his events and knocks those of his foes, on Tuesday dismissed an audience” Sen. Elizabeth Warren (D-MA) “drew the night before in New York City. Warren spoke in front of the iconic arch in the Big Apple’s Washington Square Park before an audience numbering in the ‘thousands,’ according to estimates from local media outlets.” However, Trump, speaking with reporters in California, said, “Anybody that can’t get people standing in the

middle of Manhattan in the most densely populated area of the country – anybody could do that. I think more Democrats should do it. I get these crowds in areas that nobody's ever seen crowds before. Pretty amazing."

The Hill (9/17, Easley, Samuels, 2.98M) reports that the Warren camp "estimated that 20,000 people filled Washington Square Park on Monday night to hear the candidate give a speech about how she would root out corruption in Washington if she's elected president." However, Trump "questioned whether Warren actually got as big of a crowd as her campaign claimed. 'Number one, she didn't have 20,000 people and number two, I think anybody would get a good crowd there,' he said. 'I think you have a good crowd there if you don't even go there, just say you're going and how many people are in the park.'"

The Washington Post (9/17, Parker, Linskey, 14.2M) reports, "Once widely regarded as an interesting but ultimately inconsequential novelty of political campaigns, crowd size is now a potentially meaningful metric of electability – one that can translate into volunteers, donors and, as Trump demonstrated in 2016, actual momentum. ... The multitudes who gathered after a light rain to hear Warren's plan to fix what she describes as systematic corruption – and to cheer her rebuke of Trump as 'corruption in the flesh' – provided clear evidence that Warren, even in a Democratic primary, can compete on the same terms as a president who revels in crowd size above almost all else."

Warren Draws Large New York Crowd To Hear Her Tie Trump To Washington Corruption.

The AP (9/17, Weissert) reports that the "thousands of people packed under the marble arch of Manhattan's Washington Square Park to hear...Warren on Monday" were "the product of a carefully planned, data-driven strategy to identify supporters, attract them to a rally and ultimately convert them into voters, a plan that goes well beyond producing a compelling scene for television." According to the AP, "In an era where campaigns increasingly try to leverage technology to tactical advantage, the attention to detail by Warren's team stands out." The AP says Warren has "mastered the art of drawing thousands to her rallies, but, more importantly, those turning out are also a proxy for her recent rise in the polls."

The New York Times (9/17, Burns, 18.61M) reports that in her speech, Warren "proposed a battery of new reforms in her remarks in New York City's Washington Square Park, near the 1911 Triangle Shirtwaist factory fire that she cited as an example of the oppression of the working class. And she highlighted an array of other reforms she has previously outlined, including a ban on lobbying by foreign governments and new ethics regulations on presidents and judges." According to the Times, Warren "presented herself not just as an opponent of" Trump, "whom she called 'corruption in the flesh,' but of the Washington system writ large."

Politico Analysis: Top Sanders Allies Worry He's Being Eclipsed By Warren.

Politico (9/17, Otterbein, Spiner, 4.29M) reports that some of the "fiercest supporters" of Sen. Bernie Sanders (I-VT) "are sounding the alarm that the campaign is bogged down by disorganization, personality clashes, and poor communication between state operations and national headquarters." Following two "setbacks this week – the acrimonious shakeup of his staff in New Hampshire on Sunday and loss of the Working Families Party's endorsement to Elizabeth Warren a day later – Sanders' allies and former aides are worried that recent disappointments are not one-off stumbles but rather emblematic of larger problems." However, Sanders adviser Jeff Weaver claims that "numerous rank-and-file members in the Working Families Party support Sanders and that his ground game in New Hampshire and other early states is strong."

Carter Says He Doesn't Think He Could Handle Duties Of Presidency At 80.

The AP (9/17, Barrow) reports that former President Jimmy Carter, 94, “said Tuesday he doesn’t believe he could have managed the most powerful office in the world at 80 years old.” He “didn’t tie his comments to any of his fellow Democrats running for president, but two leading 2020 candidates, Joe Biden and Bernie Sanders, would turn 80 during their terms if elected. Biden is 76. Sanders is 78. ‘I hope there’s an age limit,’ Carter said with a laugh as he answered audience questions at his annual report at the Carter Center in Atlanta. ‘If I were just 80 years old, if I was 15 years younger, I don’t believe I could undertake the duties I experienced when I was president.’”

Ocasio-Cortez Endorses Liberal Newman’s Primary Challenge To Lipinski.

Politico (9/17, Forgey, 4.29M) reports that Rep. Alexandria Ocasio-Cortez (D-NY) on Tuesday backed “liberal” Marie Newman in her 2020 primary challenged to Rep. Dan Lipinski (D-IL) – the New York lawmaker’s “first endorsement of a candidate aligned with the progressive group Justice Democrats since being elected to Congress.” Politico says “the left-wing political action committee, which aims to challenge more moderate Democratic incumbents, announced” Ocasio-Cortez’s endorsement in a tweet. The Chicago Tribune (9/17, Pearson, 2.65M) quotes Ocasio-Cortez as saying, “Marie Newman is a textbook example of one of the ways that we could be better as a party – to come from a deep blue seat and to be championing all the issues we need to be championing. The fact that a deep blue seat is advocating for many parts of the Republican agenda is extremely problematic. We’re not talking about a swing state that is being forced to take tough votes.”

Writing for the Chicago Sun-Times (9/17, 875K), Lynn Sweet says that the endorsement “by the controversial, charismatic” Ocasio-Cortez “could turn out progressives and turn off centrists in the suburban Chicago district. Lipinski’s team seemed little concerned by the popular but polarizing Ocasio-Cortez embracing Newman. I wouldn’t be surprised if Lipinski talks about Ocasio-Cortez more than Newman in the run up to the March Illinois primary. Lipinski, who will need crossover GOP voters to win the nomination in the safe Democratic district, is counting on a backlash to Ocasio-Cortez and, by extension, her provocative allies.”

The New York Times (9/17, Edmondson, 18.61M) reports that Newman unsuccessfully challenge Lipinski last year, losing “by about 2,000 votes.” The Times says Lipinski “bills himself in his campaign ads as ‘a workhorse, not a show horse,’ and the eight-term congressman, who opposes abortion rights and voted against the Affordable Care Act, has repeatedly expressed his concerns that it is ‘detrimental’ for the party to push out conservative lawmakers.” The Washington Post (9/17, Itkowitz, 14.2M) says Lipinski is “one of the last remaining conservative Democrats in Congress who oppose abortion rights,” which “has alienated him from most of the party and prompted other, more centrist Democrats...to support his challenger.” HuffPost (9/17, Miller, 1.67M) also reports on the story.

NYTimes Analysis: Some “Experts” Say Redrawn NC Political Maps Still Favor Republicans.

The New York Times (9/17, Wines, 18.61M) reports, “When a North Carolina state court struck down the state’s legislative political maps nearly two weeks ago, it said the maps had been drawn ‘with surgical precision’ to keep Republicans in control of both chambers.” Yesterday, lawmakers “approved new electoral maps – drawn under a court directive to ignore partisan considerations – that appear to give Republicans a slight political edge, some experts said.” The Times adds, “The state court that threw out the original maps will have the final say this fall and will rule on their fairness after an analysis by a Stanford University expert.”

WSJournal: Murkowski's Move To Protect Alaska's Salmon Industry Hurts Consumers.

In an editorial, the Wall Street Journal (9/17, Subscription Publication, 7.57M) takes issue with Republicans who claim to support free markets, except when competition threatens interests in their home state, specifically calling out Sen. Lisa Murkowski (R-AK) for her efforts to protect Alaska's Pacific salmon industry. The editorial criticizes Murkowski for a rider she is expected to insert in a bill this week to block the sale of genetically modified salmon. The move will hurt consumers, the Journal says, and urges Murkowski's colleagues to strip the rider from the bill.

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NIH NEWS

'Reasonable' Pricing Could Limit The Cost For Zolgensma In France. In an opinion piece for STAT

(9/18, Love, 24K) , James Love, director of Knowledge Ecology International and a board member of the of the Union for Affordable Cancer Treatment, writes that after the FDA approved Zolgensma in May, Novartis "set the price at \$2.1 million" because it can "charge whatever it wants for this therapy." While NIH Director Francis Collins "has decided to

leave pricing decisions to drug companies, without any limits," things may be different in France. Généthon, a French nonprofit research center that "holds several key patents that were licensed to AveXis, a company created to commercialize Zolgensma," included a "reasonable pricing clause," according to an unredacted copy of the license. Love says this inclusion raises the question why US charities also "don't insist on reasonable pricing agreements to protect access to the medicines they help make."

What's The Right Way To Reverse The Obesity Epidemic?

In an opinion for the New York Times (9/17, 18.61M), Spencer Bokart-Lindell discusses the "right way to reverse the obesity epidemic" in the wake of controversial "fat-shaming" comments by Bill Maher. Bokart-Lindell says, "The worldwide obesity rate has nearly tripled since 1975, according to the World Health Organization, but the problem is particularly acute in the United States: 39.8 percent of adults were obese in 2016, compared with only 15 percent in the late 1970s, according to the federal Centers for Disease Control and Prevention, the highest rate of any developed country." NIH senior researcher Kevin Hall, PhD, attributes the continued exposure of Americans to food of poor nutritional quality to what he call the "push hypothesis." Bokart Lindell concludes, "No doubt the problem requires many solutions, but all of them will have to match the scale and force of its reality."

NINR Reopens Search For Director After Nurse Backlash.

Becker's Hospital Review (9/17, Masson, 81K) reports that the National Institute of Nursing Research (NINR) on Monday reopened its search for a director after facing backlash over its appointment of dentist Lawrence Tabak, DDS, PhD, as interim director. The appointment, which "was met with immense backlash from nurses, who said NINR should be run by a nurse," was the result of "a national search earlier this year failed to identify a suitable candidate, according to NIH."

Nano-Sized Solution For Efficient And Versatile CRISPR Gene Editing.

Science Blog (9/17) reports that researchers supported by NIH have developed an alternative delivery system – nanocapsules – for CRISPR gene-editing technology, which "holds tremendous promise for treating or curing a wide range of devastating disorders, including sickle cell disease, vision loss, and muscular dystrophy." According to the study from a team that "is part of a nationwide consortium on genome editing supported by NIH's recently launched Somatic Cell Genome Editing program," nanocapsules "appear to pose a lower risk of side effects" and "can be precisely customized to deliver their gene-editing payloads to many different types of cells or

tissues in the body, which can be extremely tough to do with a virus."

'Social Jet Lag' May Contribute To Girls' Weight.

MedPage Today (9/17, Lyles, 75K) reports on a study led by "Elizabeth Feliciano, ScD, ScM, of Kaiser Permanente Northern California in Oakland," which found that the "sleep patterns and bedtimes" of teenage girls "were associated with risk of obesity." The study, which was funded by the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, and the National Institute of Diabetes and Digestive and Kidney Diseases, found that for female subjects, "each hour of 'social jet lag' – difference between weekdays and weekends in sleep midpoint, measured by actigraphy – was linked with 0.45 kg/m² greater fat mass index as assessed by dual-energy x-ray absorptiometry and a 1.19-cm larger waist circumference (P for interaction 0.01 and 0.21, respectively)." The study authors wrote, "This study suggests that female adolescents may be more vulnerable to the obesogenic effects of circadian misalignment; obesity prevention efforts should consider regular sleep-wake patterns in addition to sleep extension and sleep quality improvement."

UPMC To Receive State Grant To Study Ewing Sarcoma.

The Pittsburgh Post-Gazette (9/17, Templeton, 616K) reports that state legislators Rep. Jason Ortitay (R-South Fayette) and Rep. Tim O'Neal, (R-South Strabane) recently announced a \$100,000 state grant they landed that will enable hospital UPMC in Pittsburgh to carry out genetic research on patients with Ewing sarcoma as well as on their family members. In the next week, Rep. O'Neal "said, the State House is scheduled to vote on Resolution 483, which he authored, 'which urges Congress to direct the National Institutes of Health to conduct a comprehensive study on the causes of Ewing sarcoma.'"

Bethesda Man Will Box For Children's Cancer Funding.

Bethesda (MD) Magazine (9/17, McDonald) reports that Mike Dendas has raised nearly \$20,000 for The Children's Inn at NIH with a boxing match raised organized by national nonprofit Haymakers for Hope. Denda said that the Inn, a residential facility for children with serious illnesses and their families, was a "saving grace" during the time that his teenage cousin, Lizzie Schwanfelder, was battling clear cell carcinoma. Dendas said, "We had Yale right in our backyard and she could not get any of the treatments or they couldn't figure it out." However, Dendas said that The Children's Inn in Bethesda "had way more expertise with the type of disease my cousin was dealing with."

Wistar Wins \$4.6M NIH Grant For Studying For Studying Antibiotic Resistance. The Philadelphia Business Journal (9/17, George, Subscription Publication, 860K) reports that the National Institutes of Health has awarded the Wistar Institute In University City a \$4.6 million four-year grant to support antibiotic research being conducted by "a team of researchers led by David B. Weiner, Wistar executive vice president and director of the its vaccine and immunotherapy center." The team "is looking to advance a nontraditional approach to combat multidrug resistance by bacteria that is based on a synthetic DNA technology called DNA-encoded monoclonal antibodies."

UAB CFAR Researchers Awarded Contracts To Aid The Ending The HIV Epidemic Plan. The University of Alabama at Birmingham News (9/17, Koplon) reports that the National Institutes of Health awarded researchers from the University of Alabama at Birmingham (UAB) Center for AIDS Research (CFAR) three one-year supplemental awards totaling \$300,000 "to help develop plans for diagnosing, treating and preventing HIV in local communities, many of which are areas with high rates of new cases." The grants will enable Latesha Elope, MD, and Lynn Matthews, MD, to "help carry out the Ending the HIV Epidemic agenda set by the Trump administration to diagnose, treat and prevent HIV."

Cornell Medical School To Offer Full Scholarships For Students Who Qualify For Financial Aid. USA Today (9/17, Miller, 10.31M) reports the Weill Cornell medical school announced it would offer full-ride scholarships "for its students who qualify for financial aid." The school said in a statement that the program would begin this academic year and then continue "every year thereafter in perpetuity." Furthermore, students pursuing dual degrees as part of a separate "joint MD-PhD program will receive full tuition and stipends for living expenses from the National Institutes of Health and Weill Cornell Medicine."

Additional Source. Medscape (9/17, Brooks, Subscription Publication, 277K) reports that "first-year students in Weill Cornell Medicine's class of 2023, who entered this fall, and those in every subsequent entering class will have their student loans replaced by scholarships for their entire education." Meanwhile, "returning students who are eligible for financial aid and who matriculated prior to this year will receive scholarships that will replace their loans for this year and their remaining years as Weill Cornell Medicine medical students, the school said." The article says that there Weill Cornell "joins a growing number of medical schools offering free tuition."

Intermountain Offers Grants To Advance Genomics, Precision Medicine. Health IT Analytics (9/17, Kent) reports that Intermountain Precision Genomics is offering up to \$200,000 in grants for biomedical research projects. The grants "will provide an opportunity for scientific collaboration and offer funding toward Intermountain Precision Genomics research services, including next-generation sequencing, sample procurement, bioinformatic analysis, and other processes." Applications for the Genomic Innovation Grants "will be reviewed by a panel of scientists from different biomedical disciplines, and projects will be evaluated on the likelihood of providing scientific impact and influence on research based on NIH review criteria."

HEALTH & MEDICAL NEWS

Purdue Settlement Would Raise Money Through Further Opioid Sales. The AP (9/17, Mulvihill, Galofaro) reports Purdue Pharma's "tentative multibillion-dollar settlement" agreement "would raise money to help clean up the opioid mess by ... selling more OxyContin," which "would amount to blood money, in the opinion of some critics," and is "one reason two dozen states have rejected the deal." The article says Purdue "filed for bankruptcy Sunday in the first step toward putting the settlement into effect." The deal, which is "valued by Purdue at potentially more than \$10 billion over time," would see the Sackler family, which owns Purdue, "give up ownership of the company," which "would be reconstituted as a 'public benefit trust.' Its profits from opioids, as well as from overdose antidotes and addiction-treatment drugs, would go toward the settlement."

Georgia Health Officials Say Purdue Settlement Funds Should Go Toward Opioid Recovery. The Atlanta Journal-Constitution (9/17, Hart, 895K) continues coverage of Georgia Attorney General Chris Carr's announcement Monday that the state will accept Purdue Pharma's settlement agreement. According to the article, "Carr says the risk of fighting the deal is worse than taking what's offered and moving on." In a statement, Carr's office said, "The resources that will become available under the proposed structural framework will help Georgia combat the opioid crisis and address the needs of people living in our communities who have been devastated by the actions of those who fueled it." Likewise, "health officials said Tuesday that it's critical that the money go to substance abuse treatment and coping with the crisis." State Rep. Sharon Cooper, R-Marietta, Chairwoman of the House Health and Human Services Committee, said any money should be "used for recovery programs across our state," with "tight oversight to make sure that that's done."

South Carolina Attorney General Wilson Joins Settlement With Purdue. The Charlotte (NC) Observer (9/17, Wilks, 470K) reports, "South Carolina Attorney General Alan Wilson has joined 23 states in agreeing to a proposed, multibillion-dollar settlement with" Purdue Pharma. On Tuesday, "Wilson's office confirmed...that South Carolina was among the 24 states and five U.S. territories that have signed onto the settlement." In a statement, Wilson said the company's bankruptcy, which was announced Sunday, "was expected and is part of a settlement framework which will put one of the worst actors responsible for the opioid epidemic in our country out of business, not only in the United States, but worldwide. It will take every penny from Purdue Pharma assets and billions from the Sackler family personally."

Holdout States Vow To Challenge Purdue Pharma Settlement. The Hill (9/17, Weixel, 2.98M) reports states that have not signed on to Purdue Pharma's settlement "are gearing up for a fight in bankruptcy court and are expected to try to pursue Purdue's owners, the Sackler family, for a full accounting." In rejecting the deal, the states "criticized the settlement, saying that it is not nearly enough to address the opioid crisis and that it will take years before the full terms are realized, if at all."

Kasich, Gee: Hospitals Must Not Be Left Out Of Opioid Settlement. In an op-ed for the New York Times (9/17, Kasich, Lee, 18.61M), John Kasich, former Governor of Ohio, and E. Gordon Gee, President of West Virginia University and Chairman of the West Virginia University Health System, who are both founders of Citizens for Effective Opioid Treatment, write that the opioid crisis has imposed a "staggering" cost on hospitals, "which provide billions of dollars of unreimbursed care." Looking back to the 1998 tobacco settlement, they point out that "hospitals and front line providers" were left out. The authors hope we will "learn the lessons of the tobacco settlement and use opioid settlement funds to help those who have been at the tip of the spear in fighting the epidemic and are most needed to deal with its aftermath in the years ahead."

WPost: Proposed Purdue Pharma Settlement Does Not Serve Justice. The Washington Post (9/17, 14.2M) editorializes that plaintiffs seeking claims against Purdue Pharma are not only looking for money, but also "justice" and "accountability." However, "Purdue's proposal, which includes no new admission of wrongdoing, and which could be funded in large part from the proceeds of spinning off a Purdue international subsidiary, as well as future OxyContin sales, does not necessarily deliver that." The Post commiserates with those who are refusing to settle, and recognizes "why they would not want to settle before understanding the full nature and purpose of the \$1 billion that members of the Sackler family shuffled among trusts and overseas bank accounts, via wire transfer, in recent years."

Purdue To Stay In Business As Bankruptcy And Sackler Investigation Unfold. The AP (9/17, Sisak) reports US Bankruptcy Judge Robert Drain on Tuesday "cleared the way" for "Purdue Pharma to stay in business while it pursues bankruptcy protection and settlement of more than 2,600 lawsuits filed against it in a reckoning over the opioid crisis." The article says Purdue's "continued viability" constitutes "a key component of the company's settlement offer, which could be worth up to \$12 billion over time."

Bloomberg (9/17, Church, Hill, 4.73M) explains, "One consequence of the bankruptcy is that Purdue and its board of directors is now responsible for pursuing any so-called fraudulent transfers the company made over the years to the Sackler family." That could interfere "with any state or local officials who have either sued the Sacklers, or plan to sue them in order to recover the costs of dealing with the public health care crisis brought on by addictive painkillers. Under the U.S. Bankruptcy Code, lawsuits that could benefit creditors are considered the property of the bankrupt company."

CNN (9/18, Ly, Vitagliano, 83.16M) also covers the story.

North Carolina Files Opioid Lawsuit Against Sackler Family. The Hill (9/17, Weixel, 2.98M) reports North Carolina Attorney General Josh Stein filed a lawsuit against eight members of the Sackler family for allegedly "deliberately ignoring the harms of OxyContin [oxycodone] in order to boost the prescription painkiller's sales as well as profits for themselves." The lawsuit claims the family members were "the driving forces behind Purdue Pharma and its work to deceptively market and sell OxyContin."

Data Show Opioid-Related Deaths Declined In Maryland For Second Straight Quarter. The Washington Post (9/17, Wiggins, 14.2M) reports preliminary data released by Maryland officials on Tuesday show that fatal opioid-related overdoses in the state have declined for the second quarter in a row, marking "the first six-month drop in the last decade." Specifically, "there were 1,060 opioid-related deaths in Maryland in the first half of the year, 133 fewer...than in the first six months of 2018," which represents an 11 percent decline. Even so, "opioid-related deaths remain at nearly an all-time high in Maryland," and "the state plans to spend \$747 million in fiscal year 2020 on opioid-related programs, up from \$674 million this fiscal year. State spending on opioid-related programs has jumped by nearly 68 percent in the past three years."

HHS Awards \$2M Grant To Atlantic County Sheriff's Office For Opioid Training. The Press of

Atlantic City (NJ) (9/17, Fairfield, 177K) reports, "The Atlantic County Sheriff's Office has partnered with the Rowan University School of Osteopathic Medicine after receiving a four-year, \$2 million federal grant" from HHS' Substance Abuse and Mental Health Services Administration "to provide overdose prevention training for first responders." The sheriff's office will use the grant to train personnel throughout the county, "distribute the opioid overdose reversal drug naloxone and train overdose survivors and their families on its use." It will also use a portion of the money "to create an Atlantic County Quick Response Team that will work with the Hope One Mobile Recovery Unit operated by the Sheriff's Office," and to "enable the development of a curriculum to train first responders and community members on fentanyl safety."

Afghanistan, Iraq War Veterans Hit Hardest By Opioid Crisis, Study Finds. The Washington Examiner (9/17, Morrison, 448K) reports, "Veterans who were stationed in Afghan and Iraqi war zones after the 9/11 terror attacks have been hit hardest by the opioid crisis, according to new research" distributed by the National Bureau of Economic Research. Researchers found these veterans "have an opioid abuse rate about seven times higher than civilians who have never served in a combat zone." According to the article, researchers also "found that veterans not only deal with chronic pain that has to be treated when they return from war zones, but also post-traumatic stress that sometimes leads to drug use as a coping mechanism. ... The study's authors say that veterans didn't even have to be in the line of fire everyday to show an increased risk of opiate abuse and post-traumatic stress."

Athena Health Care Systems Will Now Accept Patients With Opioid Addictions. The Boston Globe (9/17, Freyer, 972K) reports Athena Health Care Systems, in a settlement reached Tuesday with the office of US Attorney Andrew E. Lelling, "agreed to accept patients being treated for opioid addiction, forgoing a practice that remains common among other nursing homes." Under the terms of the deal, the health system "agreed to adopt a nondiscrimination policy, provide training to admissions personnel about the rights of disabled people and opioid addiction, and pay a civil penalty of \$10,000."

Report Reveals Number Of Abortions In US Declines To Lowest Rate Since 1973. The Washington Post (9/18, Cha, 14.2M) reports, "A new Guttmacher Institute report released on Wednesday outlines dramatic changes in the abortion landscape between 2011 and 2017," and found "the U.S. abortion rate hit an all-time low – again." The report "provides detailed information by

state and region about how American women access abortion." The Post adds, "The report estimated the abortion rate in 2017...at 13.5 per 1,000 women ages 15 to 44," compared to "14.6 in 2014 and 16.9 in 2011 and is the lowest rate since the U.S. Supreme Court legalized abortion through...Roe v. Wade in 1973." The report found a total of "862,320 abortions took place in 2017 at health-care facilities," and nearly "339,640, or about 39 percent, of those were medical abortions, which involve taking pills to induce miscarriage as opposed to traditional surgical abortion."

According to the New York Times (9/18, Belluck, 18.61M), the new report "suggests that one reason for the decrease might be the growing use of long-term contraceptive methods, like intrauterine devices and implants." Additionally, researchers "tried to assess the phenomenon of women ordering abortion medications on their own, without seeking it from clinicians in the United States, as is currently required by the Food and Drug Administration, "and "found that 18 percent of nonhospital facilities reported that they had treated at least one patient for a failed attempt at a 'self-managed abortion.'"

The Los Angeles Times (9/17, Haberkorn, 4.64M) reports that the decline "comes amid a declining pregnancy rate, greater access to contraception and a significant increase in restrictions on abortion in conservative-led states."

The AP (9/18, Crary) reports, "Federal data compiled by the Centers for Disease Control and Prevention excludes California, Maryland and New Hampshire."

The Hill (9/18, Hellmann, 2.98M) also covers the report.

Researchers Discover Possible Method To Cure Common Cold. ABC World News Tonight (9/17, story 11, 0:18, Muir, 6.62M) reported that "researchers at Stanford University and UCSF" made "a discovery they hope leads to a cure for the common cold." The researchers "say disabling a single enzyme in cells may stop the virus from penetrating the cell and then spreading through the body," and add that additional research is needed.

Michigan Records Three Deaths Due To EEE. The Detroit Free Press (9/17, Shamus, 1.52M) reports three individuals in Michigan have died from Eastern equine encephalitis "and four others have been sickened by the disease, state health officials said Tuesday, amid the biggest outbreak in more than a decade." Residents in "all eight of the affected counties – Kalamazoo, Cass, Van Buren, Berrien, Barry, St. Joseph, Genesee and Lapeer counties – are urged to consider canceling, postponing or rescheduling outdoor events that occur at or after dusk, especially those that involve children, according to the Michigan Department of Health and Human Services."

Rhode Island Confirms Two More Cases Of EEE. The AP (9/17) reports, "Rhode Island officials have confirmed two more human cases of eastern equine encephalitis this season." The state's "health and environmental management departments said Tuesday two people have been discharged from the hospital and are recovering, bringing the number of human cases of the virus to three." Department officials "say a child younger than 10 years old from Coventry and an adult over 50 from Charlestown contracted the mosquito-borne disease, likely in late August."

Minnesota Department Of Health Says 11 Infected With E. Coli After Visiting State Fair. The AP (9/17) reports Minnesota Department of Health officials "say at least 11 people got sick with E. coli infections after visiting the Minnesota State Fair this summer" most likely due to contact with livestock at the Miracle of Birth exhibit. The article adds, "Six of the ill people were hospitalized, and one developed a potentially fatal complication."

The Minneapolis Star Tribune (9/16, Olson, 1.04M) also reports.

Florida Surgeon General Warns Hepatitis A Epidemic Will Not End Anytime Soon. The Miami Herald (9/17, Koh, 1.09M) reports, "Florida's ongoing hepatitis A epidemic has already far eclipsed state records, but people shouldn't expect the outbreak to end anytime soon, the state's surgeon general says." Scott Rivkees, who was recently "installed head of the state's Department of Health, told lawmakers Tuesday that 3,009 cases of the virus have been reported this year as of September 7, and that the state is still working to vaccinate hundreds of thousands of high-risk or medically vulnerable patients to curb the virus' spread." The article adds that over "200,000 people have been vaccinated this year – a huge jump from the 49,324 people vaccinated in all of 2018 – but it is unclear what fraction of those vaccinated are part of the high-risk population that federal officials recommend should be 80% vaccinated to curtail an outbreak."

Pediatric Death In California May Indicate Worse Flu Season Than Usual In US. NBC News (9/17, Edwards, 6.14M) reports that Dr. Cameron Kaiser, a public health officer for Riverside County, California, announced the death of a 4-year-old with underlying problems in the state due to the flu. Kaiser said, "A death so early in the flu season suggests this year may be worse than usual." NBC News features the opinions of various medical professionals who explain why getting the flu vaccine is so important.

Study Suggests Women Over 75 With Chronic Illnesses Can Skip Screening Mammograms. The Chicago Tribune (9/17, Gordon, 2.65M) reports new research suggests women over 75 with chronic illnesses, like heart disease or diabetes, can probably skip regular screening mammograms as they "would likely die from those conditions before developing breast cancer." Study author Dejana Braithwaite said, "For those 75 and over with chronic illness, the benefit of continued mammography is minimal. Women 75 to 84 are 123 times more likely to die of other causes than breast cancer." However, Braithwaite continued, "It's important to individualize the decision. Women should discuss with their providers the potential benefits of continuing mammography."

Aerobic Exercise May Prevent Or Slow Cognitive Decline In People At High Risk For Alzheimer's Disease, Study Indicates. CNN (9/17, Lamotte, 83.16M) reports researchers found that "a half hour of aerobic exercise four to five times a week may prevent or slow cognitive decline in older adults who are at a high risk of developing Alzheimer's" disease. The findings were published in the Journal of Alzheimer's Disease.

Study Suggests Harmful Airborne Carbon Particles Can Reach Placenta In Pregnant Women. Reuters (9/17, Emery) reports, "Airborne carbon particles that can cause health problems in adults and children are getting into the placenta as it nourishes a developing fetus, a new study has found." The study included "tissue samples from 5 pre-term and 23 full-term births" and "found that the more airborne soot the mother was exposed to during pregnancy, the higher the number of so-called black carbon particles found in the placenta, researchers report." Researchers did not conclude whether or not these particles, "created by the combustion of fossil fuels, pose a direct risk to the fetus," but they "speculate that the pollutants may play a role in the low birth weight or premature delivery more often seen in babies whose mothers are exposed to higher levels of contaminated air."

The AP (9/17, Neergaard) reports, "The Belgian researchers developed a way to scan placenta samples using ultra-short pulses from a laser that made the black carbon particles flash a bright white light, so they could be measured." The "scanning technique spotted a type of particle pollution – sootlike black carbon – on placentas donated by 28 new mothers, they reported" in the study, published in Nature Communications.

Newsweek (9/17, Gander, 1.53M) reports the mothers in the study "were categorised as living in a highly polluted area if their home was located 500 meters (1,640 feet) or less from a major road, and exposed to an average yearly

concentration of 2.42 micrograms per meter cubed of fine particulate matter during the year of their pregnancy." The article adds, "Tests revealed the women who lived in the highly polluted areas had more black carbon particles in their placentas," yet researchers "found black carbon in all of the placentas."

The Hill (9/17, Gstalter, 2.98M) and CNN (9/18, Yeung, 83.16M) also cover the study.

Medical Experts Urging Use Of Precision Medicine To Identify Genetic Causes Of Disease, Tailor Therapies. The Washington Times (9/17, Tan, 492K) reports, "Medical experts and researchers are urging for the use of precision medicine to help identify genetic causes of disease and to tailor therapies for individual patients." In doing so, "physicians could pinpoint the biomarkers of a disease in a patient and apply treatments that work best based on that person's genetic profile, instead of relying on a traditional 'one-size-fits-all' approach, researchers said Tuesday in panel discussion." The use of precision medicine has already "been applied in cancer diagnosis and treatment."

Fluoroquinolone Antibiotics May Increase The Risk Of Heart Valve Problems, Study Indicates.

The New York Times (9/17, Bakalar, 18.61M) reports, "The class of antibiotics called fluoroquinolones (Cipro, Levaquin and others) may increase the risk of heart valve problems," researchers concluded after examining "antibiotic use among 12,502 people with heart valve regurgitation," then comparing "them with 125,020 healthy controls." The findings were published in the Journal of the American College of Cardiology.

North Carolina Children's Hospital To Resume Performing Complex Heart Surgeries.

The New York Times (9/17, Gabler, 18.61M) reports North Carolina Children's Hospital "that stopped performing complex heart surgeries in recent months after high death rates were disclosed may now resume the procedures, according to an advisory board that was examining the hospital's practices." The advisory board "noted 'significant investment and progress' had been made at" the hospital "while suggesting areas for improvement, including increasing the number of surgeries performed, a factor associated with better outcomes." The report released by the board "was one of several initiatives launched by UNC Health Care in response to a New York Times investigation in May that detailed turmoil at the medical institution in 2016 and 2017."

Rural Maine Hospital Files For Bankruptcy Protection. The Bangor (ME) Daily News (9/17,

Sambides Jr., 198K) reports Calais Regional Hospital in Maine "filed for Chapter 11 bankruptcy protection on Tuesday, but hospital officials promised that the 25-bed facility would stay open as the bankruptcy case proceeds." The Regional Hospital "blamed the bankruptcy filing in U.S. Bankruptcy Court in Bangor on a number of factors, including a drop in paying and insured patients; increased levels of care the hospital has had to provide for free; inadequate reimbursement from MaineCare, the state's Medicaid program; and increasing regulatory requirements." The filing "comes 11 days after the hospital's nursing staff voted to put the option of a strike on the table in contract negotiations that have dragged on for almost a year," and is the "second rural Maine hospital to file for bankruptcy protection this year."

Hospitals' Means To Collect Unpaid Bills Highlighted.

CBS News (9/17, Cerullo, 3.68M) reports, "Some hospitals are using increasingly aggressive means to collect on unpaid bills, including garnishing patients' wages and forcing them to sell their homes." The article highlights the University of Virginia Health System, which "filed roughly 36,000 lawsuits against patients over six years" and the "Carlsbad Medical Center in New Mexico," which "has sued more than 3,000 patients over 10 years." The article says hospitals across additional states "have employed the same tough tactics."

Vaccine Protesters In California Co-Opting Civil Rights Mantle.

Politico (9/18, Mays, 4.29M) reports that protesters in California who are opposed to childhood vaccine mandates have "co-opted the civil rights mantle from the 1960s, insisting that their plight is comparable to what African Americans have suffered from segregationist policies." This month, hundreds of vaccine protesters throughout the state have galvanized "against legislation that would crack down on medical exemptions to childhood immunizations."

Group Of Senators Urge FTC To Scrutinize Pharma Industry Mergers.

Reuters (9/17, Sibi Joseph) reports Sen. Amy Klobuchar (D-MN) on Tuesday "led a letter by U.S. senators that urged the Federal Trade Commission (FTC) to closely scrutinize pharma mergers, raising concerns about the potential harm to customers." The deals "proposed by AbbVie and Bristol-Myers raise significant antitrust issues, the senators wrote, calling on the FTC to 'take appropriate action' to protect consumers from mergers that may threaten competition, raise drug prices or reduce patient access to essential medications." Ed Silverman in his "Pharmalot" column for STAT (9/17, Silverman, 24K) reports the lawmakers "noted there has been a 'steady increase' in mergers and acquisitions in the pharmaceutical industry and

also pointed to multibillion-dollar deals announced earlier this year by Pfizer (PFE) and Roche (RHHBY)."

AARP Wages Multimillion-dollar Campaign Against Pharmaceutical Industry. STAT (9/17, Florko, 24K) highlights AARP's "multimillion-dollar campaign against the pharmaceutical industry and its high prices." AARP Senior Vice President of Campaigns John Hishta described the Stop Rx Greed campaign as "an all-hands-on-deck effort to raise the profile of the issue and to encourage action." AARP Executive Vice President and Chief Advocacy and Engagement Officer Nancy LeaMond said of the campaign, "We saw alignment in four key areas: families in great need, policymakers on both sides looking for solutions, a workable legislative calendar, and an out-of-touch industry that can't even admit there's a problem."

GLOBAL HEALTH NEWS

South Korea Confirms Second Case Of African Swine Fever At Pig Farm Near North Korea Border. Reuters (9/17, Chung) reports South Korea "confirmed a second case of African swine fever at a pig farm near the border with North Korea, a day after reporting its first-ever outbreak of the virus." South Korea's "Ministry of Agriculture, Food and Rural Affairs said in a statement on Wednesday that the second case was detected at a farm in Yeoncheon, northwest of the capital Seoul, where 4,700 pigs had been raised." Furthermore, the ministry said all pigs on the farm would be slaughtered.

Explosion Reported At Russian Laboratory That Holds One Of The World's Two Live Samples Of Smallpox. USA Today (9/17, Yancey-Bragg, 10.31M) reports that on Monday there was an explosion at the Russian State Centre for Research on Virology, "one of two places in the world that holds live samples of the smallpox virus." The article says that "a gas cylinder exploded on the fifth floor of a six story laboratory building at the" facility causing a fire.

CNN (9/17, Regan, 83.16M) reports the lab said in a statement that there was no biohazardous material being stored in the room where the explosion happened.

North Macedonia Turning To Growth Of Medicinal Marijuana For Economic Boost. Reuters (9/17, Sekularac) reports North Macedonia "legalised the growth of cannabis for medicinal purposes in 2016, joining a growing number of countries to have done so or be about to do so, such as Britain, Greece, Thailand and some U.S. states." Since 2017, the country "has issued 28 licences

for growth and production of cannabis oil and another 15 companies are waiting for permits," yet "very little has been produced and no exports have been made as producers hone their skills."

France To Offer Free Iodine Tablets To People Living Near Nuclear Plants. Reuters (9/17, De Clerq) reports, "France will offer free iodine tablets to around 2.2 million people living close to nuclear plants to help protect them from radiation in case of an accident." ASN, the country's nuclear regulator, "said on Tuesday people living within 10-20 km of one of utility EDF's 19 nuclear plants, as well as some 200,000 institutions such as schools, will receive a letter in coming days informing them that they can pick up free iodine tablets from pharmacies."

While Childhood Mortality Has Fallen Overall, Some Places Still Have High Rates. Josh Katz, Alicia Parlapiano, and Margot Sanger-Katz write in "The Upshot" blog for the New York Times (9/17, 18.61M) that childhood mortality has been "nearly cut in half" over the past two decades, "but the results" of international efforts "are also highly imbalanced." The piece explains that "in some places, children's health has improved drastically," but "in others, many still die very early."

HHS IN THE NEWS

New York Becomes First State To Ban Sale Of Flavored E-Cigarettes. ABC World News Tonight (9/17, story 4, 0:55, Muir, 6.62M) reported that New York state approved "an emergency ban on sales of most flavored e-cigarettes, and it comes as we learn tonight of yet a seventh death now linked to vaping."

The AP (9/17, Hajela, Klepper) reports that New York "became the first state to ban the sale of flavored e-cigarettes Tuesday, a move that comes as federal health officials investigate a mysterious surge of severe breathing illnesses linked to vaping." The vote by the state Public Health and Health Planning Council "means the prohibition, which covers flavored e-cigarettes and other vaping products except for menthol and tobacco flavors, goes into effect immediately. Retailers will have two weeks to remove merchandise from store shelves."

The Wall Street Journal (9/17, West, Subscription Publication, 7.57M) reports that some members of the council said they were conflicted about signing off on the emergency measure and others said they would have preferred that it include menthol flavoring.

CNN (9/17, Christensen, 83.16M) reports that the ban "would stand for 90 days as a piece of emergency legislation" and "would need to be renewed to continue." The only two

flavors customers "will be able to buy are tobacco and menthol." New York state Health Commissioner Dr. Howard Zucker "said in the emergency meeting that officials would take a closer look at menthol to decide whether it should be banned as well."

The New York Post (9/17, Narizhnaya, Hogan, Fonrouge, 4.57M) reports that "the New York State Vapor Association, a trade group representing 700 independent vape shops across the state, held a series of events across the state announcing they're considering legal options to fight" the ban, which was proposed Sunday by Gov. Andrew Cuomo (D).

Also reporting on the story are: Reuters (9/18, Dobuzinskis), The Hill (9/17, Axelrod, 2.98M), Forbes (9/18, Lee, 9.71M), the Albany (NY) Times Union (9/17, Bump, 457K), the New York Post (9/17, Hogan, Fonrouge, 4.57M), the Lower Hudson Valley (NY) Journal News (9/17, Robinson, 328K), the New York Daily News (9/18, Shahrighian, 2.52M), and the Buffalo (NY) News (9/17, McNeil, 391K).

States, Localities Rush To Limit Vaping, But Experts Say Effect Uncertain. The New York Times (9/17, Williams, Del Real, 18.61M) reports, "After a spate of illnesses linked to vaping, states are rushing to push through bans on e-cigarettes for anyone under 21. Governors are calling for prohibitions on flavors like bubble gum, cotton candy and banana split, which critics say are meant to entice young people into trying vaping. And in some states, lawmakers are contemplating raising taxes on vaping products as a way to discourage their use. Yet amid the flood of new measures from state leaders as well as mayors, experts said it was uncertain how much immediate or lasting effect the provisions would have on a broad and growing range of concerns about vaping."

The Cleveland Plain Dealer (9/17, Hancock, 895K) reports that Ohio Gov. Mike DeWine (R) "said Tuesday his legal team is looking to see whether he has the authority to ban flavored e-cigarettes." DeWine "told cleveland.com, 'This is a public health crisis,' noting that more than a dozen Ohioans aged 16 to 26 have been hospitalized with severe lung disease because of vaping. Nationwide, seven people have died recently from a vaping-related illness."

Politico (9/17, Colliver, 4.29M) reports that several California cities "are swiftly moving beyond flavored vape bans to outlaw e-cigarette sales entirely, following in the footsteps of Juul's hometown of San Francisco." JUUL Labs "already has spent more than \$4.5 million trying to convince voters to overturn San Francisco's first-in-the-nation e-cigarette ban with a November ballot initiative." If San Francisco's broad ban "prevails at the ballot box, it will likely encourage more cities and states to take bold measures."

The Washington Post (9/17, Nirappil, 14.2M) reports DC lawmakers on Tuesday "proposed sweeping measures to

curb the rise of youth vaping, including a ban on flavored e-cigarettes and requiring a prescription to buy other electronic smoking products." A bill "introduced by D.C. Council Member Vincent C. Gray (D-Ward 7) would ban the sale of vaping products at any location that is not a medical marijuana dispensary or a pharmacy. The District would be the first U.S. jurisdiction with such stringent restrictions on e-cigarette sales."

JUUL Product Sales Halted In China Days After They Were Launched. The Wall Street Journal (9/17, Maloney, Subscription Publication, 7.57M) reports that sales of JUUL Labs products in China have been halted just days after they launched on ecommerce sites JD.com and Tmall. Juul representatives said they are in contact with the sites' owners but don't know why sales were stopped.

Bloomberg (9/17, Huet, 4.73M) reports the company "said it wants to make the products available again in the world's largest tobacco market." Victoria Davis, a spokeswoman for Juul, said in an emailed statement: "We remain steadfast in our commitment to providing the more than 300 million adult smokers in China with a viable alternative to combustible cigarettes."

Reuters (9/17, Soundarya, Kirkham) reports that the company "is aggressively expanding in international markets including China."

Forbes (9/17, Voytko, 9.71M) reports, "There are over 300 million smokers in China, and nearly 60% are male, according to the World Health Organization. In 2018, around 2.4 trillion cigarettes were sold in the country through China National Tobacco, a state-run monopoly."

US, UK View Vaping Very Differently. CNN (9/17, Hunt, 83.16M) reports that while the Trump Administration has "moved to ban e-cigarette flavors and there are warnings to avoid vaping altogether," in the UK, e-cigarettes "have been embraced mostly as a way for adults to quit combustible cigarettes. Indeed, health authorities in the UK stand by their support for e-cigarettes as a cessation tool." The difference in attitude appears to be related to "regulation, especially on advertising and promotion, and the levels of nicotine in vaping products."

Policy Expert Argues Market Model For Vaping, Marijuana Harms Young People. In an opinion piece for The Hill (9/17, 2.98M), Meryl Justin Chertoff, the incoming Executive Director of the Georgetown Project on State and Local Government Policy and Law, writes that "rather than limiting access using a medical model – allowing vaping only by prescription and with strict controls against youth use – vaping was introduced on a market model," and the "marketing appears to have been targeted at young people." Chertoff says "laxity by state regulators and legislators has allowed the industry to market e-cigarettes to American kids," resulting in "apparent vaping-related deaths and lung damage to young people and a new generation with an addiction

problem." Chertoff adds that "states also should be reviewing their pot laws, reconsidering the wisdom of letting markets compete for use by teenagers."

Seventh Person Dies From Lung Illness Tied To Vaping. NBC Nightly News (9/17, story 4, 1:25, Holt, 5.96M) reported on "the death of another patient from a serious illness related to vaping." The California man, aged 40, died from severe pulmonary injury, according to health officials. It is the seventh reported death from lung illness tied to vaping. Currently, "the CDC is investigating 380 cases across 36 states, and has activated its emergency operation center, directing more staff and resources to the problem."

The Washington Post (9/17, Epstein, Sun, 14.2M) reports "the unnamed Tulare County man died of 'complications related to the use of e-cigarettes,' according to the county Health and Human Services Agency." The patient "had been in the hospital for 'several weeks' before his death, said department spokeswoman Jan Winslow." The man "had a history of vaping, though Winslow said officials were still investigating what products he used."

Two More Cases Of Vaping-Related Lung Disease Identified In Washington State. The Oregonian (9/17, Zarkhin, 1M) reports that "two new cases of the severe lung disease related to e-cigarettes have been identified in Washington, raising the number of victims in that state to three, health officials said Tuesday." The victims were "both in Spokane County" and were both "young – one patient was under 20 and another was between 20 and 29 years old." Still, "no specific product or device has yet been identified, according to the Washington State Department of Health."

The Seattle Post-Intelligencer (9/17, Guevara, 430K) reports Washington State Health Officer Kathy Lofy said in a news release, "This is now a state-wide outbreak." The patients "all exhibited symptoms indicating lung disease and reported vaping before becoming sick."

Two More Cases Of Vaping-Related Respiratory Illness Reported In Oregon. The AP (9/17) reports that "state officials say two additional cases of respiratory illnesses linked [to] vaping have been reported, bringing the total number of cases in Oregon to four." The new cases follow state health officials' announcement "that an Oregonian died in July from a respiratory illness tied to vaping." Officials have not "provided details about the three other people's illnesses or where they were treated."

Arizona Identifies Three Cases Of Vaping-Related Respiratory Illness. The AP (9/17) reports that Arizona "health officials say three cases of vaping-related respiratory illness have been identified in" the state, all in Maricopa County. According to the state Department of Health Services, "the people involved in all three cases in Arizona were hospitalized but have since been discharged." The AP

adds that the federal CDC "says investigators haven't any specific substance or vape product linked to all cases."

The Arizona Republic (9/17, Innes, 869K) reports that "in all three cases, the patients were males in their 20s." A Maricopa County Department of Public Health spokeswoman "said in the local cases, the patients vaped products with nicotine and cannabinoids."

Vermont Confirms First Case Of Severe Respiratory Illness Linked To Vaping. The Burlington (VT) Free Press (9/17, Syed, 125K) reports that Vermont's "health department confirmed its first case of severe respiratory illness associated with vaping." Currently, "investigations are underway regarding five more potential cases."

VT Digger (VT) (9/16, French, 4K) also reported on the story.

Pulmonologist Documented Case Of Vaping-Related Pneumonia Eight Years Ago. The Portland (OR) Business Journal (9/17, Hayes, Subscription Publication, 827K) reports that "eight years ago, long before the current health scare from e-cigarettes, a pulmonologist...documented a case of vaping-related pneumonia." A woman, aged 42, was admitted to a hospital "after shortness of breath, cough and fevers." The woman's "respiratory symptoms had started about seven months earlier, when she began using e-cigarettes." She "had lipoid pneumonia," and "the suspected source was 'recurrent exposure to glycerin-based oils found in e-cigarette nicotine vapor,' according to" a study published in the journal *Chest*.

Boston Doctors Believe Vaping Crisis Is Being Under-reported. The Boston Globe (9/17, Martin, 972K) reports Boston Children's Hospital has seen seven patients "over the past year and a half believed to be suffering from vaping-related lung illness that has recently roiled the country, leaving seven dead and 380 hospitalized." According to the article, "the exploding outbreak, linked to 38 possible cases in Massachusetts, has raised questions about why it's happening now, when vaping has been popular for years." Doctors in the Boston area "believe the vaping-related lung injuries have been going on much longer and affected far more people than officially reported." They point to "a host of reasons for the current crisis: toxic chemicals in the supply chain of vape products; clinicians previously only asked patients about cigarettes, not vaping; and more people are vaping now."

Azar Met With Ugandan Minister Of Health. Eagle Online (UGA) (9/17, Serugo) reports in continuing coverage that HHS Secretary Azar "has met with the Ugandan Minister of Health Jane Aceng and toured key public health response centers." Azar and Aceng "discussed the Ugandan government's successful response to recent isolated cases of Ebola in the country, and ongoing efforts to control the spread of the Ebola outbreak." Minister Aceng

also "hosted Secretary Azar...on a tour of the Uganda National Institute of Public Health, including the Public Health Emergency Operations Center and the Field Epidemiology Training Program, a program supported by the Centers for Disease Control and Prevention." The piece adds that Azar "also visited the Uganda National Health Laboratory Service (UNHLS)," and "Secretary Azar spoke with Minister Aceng and UNHLS officials about how the U.S. government can continue to support research at the UNHLS."

PML Daily (UGA) (9/18) reports "Azar assured President Museveni of the USA's continued support to Uganda in combating infectious diseases." The piece says that "Museveni [appreciates] the USA's role" because through the US CDC, "Uganda is able to obtain a modern laboratory."

Azar Asks Tanzania For Transparency On Case Of Woman Who Died From Unknown Illness.

The Daily Nation (KEN) (9/17, Merab, 5K) reports in continuing coverage that on Monday, HHS Secretary Azar "asked [the] Tanzanian government to disclose information about a woman who died from what the World Health [Organization] termed as an unknown illness." Azar added that Tanzania "has refused to avail samples from the deceased for testing, nor has it made available other information about them."

Azar Led Delegation To Ebola Treatment Center In DRC.

Homeland Preparedness News (9/17, Kovalski) reports HHS Secretary Azar "led a contingent of U.S. officials on a tour last week of an Ebola treatment center" in Butembo, Democratic Republic of the Congo, "observed the detection, infection prevention, and control measures," and "shared his sincere gratitude for the hard work and dedication all personnel have shown in the face of this health crisis."

Some Brokers Selling Poor Insurance Policies Under ACA Exemptions.

Bloomberg (9/17, Darie, 4.73M) reports that "some brokers are taking advantage" of changes to health insurance rules made by the Trump Administration, "selling plans so skimpy that they offer no meaningful coverage." Bloomberg quotes HHS Secretary Azar as saying, "These plans aren't for everyone, but they can provide a much more affordable option for millions of the forgotten men and women left out by the current system." Bloomberg cites Health Insurance Innovations as "the center of the market." The company, Bloomberg says, "sought to provide a clearinghouse for brokers who sold cheap insurance to individuals." Bloomberg focuses on the experience of one couple who bought a policy that paid just \$4,000 for heart surgery, leaving them with bills of over \$200,000, and, Bloomberg adds, "similar stories aren't hard

to find." Bloomberg also reports that the couple now has "a comprehensive, ACA-compliant insurance policy" that "costs less than they were paying for junk insurance."

Tennessee Proposes Block Grant Reform For Medicaid.

The Washington Post (9/17, Goldstein, 14.2M) reports, "Tennessee unveiled a plan on Tuesday to convert Medicaid into a block grant" which has been "long supported by conservatives," but which the Post says "would rupture the federal government's half-century-old compact with states for safety-net insurance for the poor." CMS Administrator Seema Verma, the Post adds, "has urged states to move toward block grants." Tennessee is the first state to submit a block grant proposal. Under its proposal, TennCare, the state's Medicaid program, would use a block grant "for medical services for children, pregnant women, parents and other core groups of people such as those who are blind and disabled," while "coverage of prescription drugs and payments to hospitals that treat a large share of low-income patients" would not be affected. Under the proposal, "if the state spent less in a given year than it would have under the traditional Medicaid system, Tennessee would split those savings" with the federal government.

The Wall Street Journal (9/17, Armour, Subscription Publication, 7.57M) reports Tennessee Gov. Bill Lee (R) told the Journal the state intends to follow Administration policy in seeking greater innovation of services and efficiency. The Journal adds that Tennessee's draft proposal will have a comment period and a final proposal will be submitted in November.

CNN (9/17, Luhby, 83.16M) reports on its website that CMS spokesman Johnathan Monroe said, "CMS supports efforts to improve accountability for cost and outcomes in Medicaid, and we look forward to working with Tennessee once they submit their proposal to help them achieve these goals as effectively as possible within our statutory authority."

The Chattanooga (TN) Times Free Press (9/17, Sher, 171K) reports Tennessee estimates the block grant would be "a \$7.9 billion annual lump sum," and promises "to share future anticipated savings in TennCare on a 50/50 basis with the federal government." Lee believes the proposal "could provide upwards of \$1 billion for Tennessee" that could be used for "health care, including rural health initiatives," or for "select expansion of TennCare to new population categories." Tennessee will hold "three public hearings in each of the state's three grand divisions in the cities of Knoxville, Nashville and Jackson." The Times Free Press adds, "A 30-day public comment period is in place before the actual Medicaid Section 1115 waiver for TennCare can be submitted to federal officials."

The Hill (9/17, Weixel, 2.98M) reports HHS Secretary Azar "told lawmakers last spring that he had been having conversations with states interested in the idea."

CQ Roll Call (9/17, Raman, 154K) reports, "Under the state's waiver plan, Tennessee would gain the flexibility to adjust its Medicaid program in new ways without needing federal approval for each change," though it "would not change who is eligible for some types of coverage or which benefit categories are offered under Medicaid."

The Daily Memphian (TN) (9/17, Stockard) reports, "Congress has not approved a block grant program, and there's no guarantee the feds will agree to share any savings the state finds."

Modern Healthcare (9/17, Luthi, Subscription Publication, 214K) reports, "patient advocates are blasting" the proposal "as undercutting core guarantees for patients without any accountability."

The Nashville (TN) Business Journal (9/17, Stinnett, Subscription Publication, 844K) reports Gov. Bill Lee "said the state has spent less than projected in each of the last 10 years."

The Tennessean (9/17, Allison, 458K) reports, "The savings estimate is based on recent data on annual spending by TennCare."

FierceHealthcare (9/17, King, 146K) reports Tennessee said the plan "does not rely on reductions to eligibility or benefits in order to achieve savings."

Axios (9/17, Ayesh, Owens, 521K) says that if it is approved and implemented, it "would be a radical change to the medical safety net for the nation's poorest citizens."

The Fiscal Times (9/17, 3K) also reports on the story.

FDA Hosts Public Hearing To Discuss Standards For Future Opioid Analgesic Approvals. Politico (9/17, Owerhohle, 4.29M) reports in its Prescription PULSE section that the FDA hosted a public hearing yesterday "to discuss standards for future opioid analgesic approvals, along with incentives for new (and non-opioid) pain and addiction medicines." At the event, Public Citizen's presenter spoke on the FDA's "Woefully Inadequate in Substance, Devoid of Necessary Urgency" opioid framework. Also, "pharmaceutical companies and the trade group BIO will also weigh in on incentives – or lack of them – to make new pain options."

Roche's Obinutuzumab Receives FDA Breakthrough Therapy Designation For Lupus Nephritis. Reuters (9/18, Miller) reports Roche has been awarded "the U.S. Food and Drug Administration's breakthrough therapy tag for its drug Gazyva [obinutuzumab] in lupus nephritis, the Swiss drugmaker said on Wednesday, boosting its efforts to recycle the 2013-approved lymphoma

medicine for new indications." Currently, "there are no FDA-approved drugs for lupus nephritis, a life-threatening manifestation of the autoimmune disease lupus in which the kidneys grow inflamed." Sandra Horning, Roche's Chief Medical Officer, said, "We are committed to developing Gazyva as a potential new therapy for lupus nephritis and plan to begin enrolling patients in a phase III trial next year."

Hospitals Challenge HHS Regulation That Reduces Funding For Hospitals Training Medical Fellows. Bloomberg Law (9/17, Pazanowski, Subscription Publication, 4K) reports 32 hospitals have filed a lawsuit against the Department of Health and Human Services seeking "to invalidate a new regulation that reduces the money they receive for training medical fellows." The hospitals claim that the "new regulation imposes a 'fellow penalty' on hospitals that receive compensation for the part of the costs they incur in training residents that is attributable to treating Medicare beneficiaries."

Federal Judge Tosses Out CMS Action On Hospital Outpatient Payments. Bloomberg Law (9/17, Wheeler, Pugh, Subscription Publication, 4K) reports behind a paywall that a federal district court judge in the District of Columbia "tossed out a Trump administration scheme that lowered how much off-campus, hospital-based clinics can get paid for treating Medicare patients." The US District Court for the District of Columbia "said the Centers for Medicare & Medicaid Services, part of the Department of Health and Human Services, 'exceeded its statutory authority when it cut the payment rate for clinic services at off-campus provider-based clinics.'"

Columnist Argues Right-To-Try Erodes Authority Of FDA And Undermines Public Health. Michael Hiltzik writes in his daily business column for the Los Angeles Times (9/17, 4.64M), "The federal right-to-try law, signed by President Trump in May 2018...always was a cruel sham perpetrated on sufferers of intractably fatal diseases." Although, Hiltzik adds, "the law was promoted as a compassionate path to experimental treatments for those patients," it was, he says, "a cynical ploy aimed at emasculating the Food and Drug Administration in a way that would undermine public health and harm all patients." Hiltzik also accuses President Trump of "making up claims about the law," and doing so during a "White House event on Sept. 11...while Health and Human Services Secretary Alex Azar and Acting FDA Commissioner Ned Sharpless sat silently by nearby." Hiltzik concludes, "right-to-try was the first step in eroding the authority of one of the nation's most important agencies safeguarding public health."

NATIONAL FRONT PAGE NEWS

Headlines From Today's Front Pages.

WALL STREET JOURNAL:

Saudi Arabia Set To Return To Normal Oil Production Levels By End Of Month

Fed Intervenes To Curb Soaring Short-Term Borrowing Costs Streaming War Spurs Classic TV Arms Race

'Nobody Has To Be Punished': Joe Biden's Economic Tap Dance

Spotted Lanternfly VS. Pennsylvania: The Bug Is Winning

NEW YORK TIMES:

After Tight Israeli Election, Netanyahu's Tenure Appears Perilous

Trump To Revoke California's Authority To Set Stricter Auto Emissions Rules

To Find Clues In Saudi Oil Attacks, US Examines Missile And Drone Parts

Trump's Challenge: Can His Word On Iran Be Trusted?

Cokie Roberts Dies; Veteran Broadcast Journalist Was 75

Almost Everywhere, Fewer Children Are Dying

WASHINGTON POST:

Pompeo flying To Mideast For Talks

EPA To Curtail Calif. Air Rules

Pioneer, Champion Of Women In Media

Vaping Industry Goes Into Crisis Mode After Trump Ban

New Focus On Crowd Size As Warren Rally Rivals Trump's In Israeli Exit Polls, No Clear Winner

FINANCIAL TIMES:

Johnson To Abide By Any Supreme Court Ruling On Recalling MPs

Bill Gates: Fossil Fuel Divestment Has 'Zero' Impact

Saudi Oil Attack Highlights Middle East's Drone War

Fed Plans Second Intervention To Ease Funding Squeeze

WASHINGTON TIMES:

Trump Rejects Iran Meeting, Looks Past Sanctions To 'Restore Deterrence'

Iran Clash Distracting Trump From Advancing North Korea Nuke Deal, South Korea Officials Fear

Defiant Lewandowski Infuriates Dems, Delights Trump: 'Thank You, Corey'

Top Democrats Rush To Squash Kavanaugh Impeachment Push

IG Report Details Andrew McCabe's FBI leaks, Secretive Media Campaign And Cover-Up

STORY LINEUP FROM LAST NIGHT'S NETWORK NEWS:

ABC: Tropical Storm Imelda; Teens Arrested For High School Shooting Plot; MLB-Pittsburgh Pirates Pitcher Arrested; New York-Flavored E-Cig Ban; Saudi Arabia-Oil Facility Attack; Corey Lewandowski-Testifying On Capitol Hill; Remembering Cokie Roberts; Alex Trebek Interview; NYC-Domestic Call Turns Into Shootout; Montana-Grizzly Bear Attack; Potential Cure For Common Cold; Cokie Roberts-Her Own Words.

CBS: Tropical Storm Imelda; Saudi Arabia-Oil Facility Attack; Mike Pompeo-Saudi Arabia Trip; Afghanistan-Green Beret Killed In Combat; Afghanistan-Suicide Attacks; Syria-ISIS Fighters; Israel-Election; Corey Lewandowski-Testifying On Capitol Hill; MyPayrollHR Shutdown; UN-Climate Crisis Summit; Colorado Woman Swims Across English Channel Four Times; Remembering Cokie Roberts.

NBC: Tropical Storm Imelda; Saudi Arabia-Oil Facility Attack; Israel-Election; New York-Flavored E-Cig Ban; Afghanistan-Green Beret Killed In Combat; Teens Arrested For High School Shooting Plot; Corey Lewandowski-Testifying On Capitol Hill; Amazon-Job Fairs; Remembering Cokie Roberts; Climate Change-Warming Waters; MyPayrollHR Shutdown; NFL-Antonio Brown; Colorado Woman Swims Across English Channel Four Times.

NETWORK TV AT A GLANCE:

Remembering Cokie Roberts – 7 minutes, 45 seconds

Saudi Arabia-Oil Facility Attack – 6 minutes, 20 seconds

Tropical Storm Imelda – 3 minutes, 45 seconds

Corey Lewandowski-Testifying On Capitol Hill- 3 minutes, 40 seconds

STORY LINEUP FROM THIS MORNING'S RADIO NEWS

BROADCASTS:

ABC: Corey Lewandowski-Testifying On Capitol Hill; Mike Pompeo-Saudi Arabia Trip; New York-Flavored E-Cig Ban; Teens Arrested For High School Shooting Plot.

CBS: Mike Pompeo-Saudi Arabia Trip; Tropical Storm Imelda; GM-Strike; Corey Lewandowski-Testifying On Capitol Hill; Remembering Cokie Roberts.

FOX: Corey Lewandowski-Testifying On Capitol Hill; New York-Flavored E-Cig Ban; Hurricane Humberto.

NPR: Mike Pompeo-Saudi Arabia Trip; Israel-Election; US Abortion Rates Down; New York-Flavored E-Cig Ban.

LAST LAUGHS

Late Night Political Humor.

Trevor Noah: [On Sean Spicer's performance on 'Dancing With The Stars'] "Let's kick it off with Sean Spicer, former press secretary and human Dilbert. Like most people President Trump hires, Spicer left the administration with his

reputation in tatters. But if there's one thing American loves, it's a comeback. ... It sounded like the judges did not like Spicer's dancing, or at least that's how last night. But today, Sean Spicer said it was actually the best performance they had ever seen of all time."

Trevor Noah: "Honestly, I think Spicer will be perfect for 'Dancing With The Stars.' Yeah, pretend you know what you're doing till you get kicked out. It's just like working for Trump."

Trevor Noah: "The presidential race. Even though we have been in primary season for six years, we're still 11 months away from seeing one Democrat face off against Donald Trump. But last night, we might have got an sneak peek to the general election, because last night, Elizabeth Warren and Donald Trump held dueling campaign rallies on opposite sides of the country."

Trevor Noah: "So let's start with Elizabeth Warren, Massachusetts Senator and mom who knows all the two-letter words in Scrabble. ... After her speech, Elizabeth Warren spent four hours taking selfies with her supporters. It took three hours to get most of the crowd, and then an extra hour for that one annoying person who's never satisfied. 'Oh, no, wait, I look weird. Do it again. Let's try portrait mode. Now one with funny faces. Aaaahhh! Oh, memory is full, let me delete a podcast, hold on, hold on.'"

Trevor Noah: [On Trump's rally, asking Steve Cortes about loving the country and Hispanics] "While Elizabeth Warren was taking over New York, Donald Trump was doing his campaign rally in New Mexico, a solidly blue state with a Hispanic population, which is probably why he tried to tailor his speech to the crowd, and it got a little uncomfortable. ... What...was that? 'What do you like more, the country or Hispanics?' Those two things aren't even in the same category! What do you like better, Pepsi or Mongolia, huh? It's also a [bad] question, because it implies that Hispanics aren't a part of the country, right? And what's amazing is, it was still somehow only the second-most-offensive thing Trump said...because Trump also said he was confused by his Hispanic friend who looks too white. He said, 'I don't get it, how come you're not wearing a sombrero or dancing the salsa? You're less Hispanic than Sean Spicer!'"

Trevor Noah: "Am I the only person who feels Donald Trump uses these rallies as his personal therapy sessions? Pretty soon he's just going to come out on a couch telling us his pain. (As Trump) 'Who here wasn't hugged by their father? What do you like more, Hispanics or your fear of dying alone?'"

Conan O'Brien: "True story: Today, President Trump visited Los Angeles in an attempt to raise money for his 2020 re-

election campaign. He's in town raising money, that's right. Ladies and gentlemen, he raised \$48."

Jimmy Kimmel: "Welcome to Los Angeles, California, where the traffic today is even more terrible than the usual terrible because we have a special visitor in town. You know? We're at Code Orange right now, because President Trump is here. It's weird to think that right now, the President of the United States is lurking just a few miles away from here in his hyperbaric tanning chamber, eating all our Popeye's chicken sandwiches, but he is."

Jimmy Kimmel: "Trump is at a fundraiser in Beverly Hills and had a meet-and-greet in Palo Alto where tickets went up to \$100,000. You get a round table discussion, a photo op, and what they billed as premiere seating for lunch. What is 'premiere seating for lunch' with Donald Trump? You get to join him in his booth at Carl's Jr.?"

Jimmy Kimmel: [On Trump's rally, asking Steve Cortes about loving the country and Hispanics] "Our traffic-cone-in-chief was in New Mexico last night for a rally that celebrated his version of diversity. ... 'There's nobody that loves Hispanic more.' I know he doesn't speak Spanish, but now he's not even speaking English."

Jimmy Kimmel: "The Democrats still aren't fully on board with impeachment, because they know no matter what happens in the House, Trump will be saved by the Republican Senate. So a lot of them say, 'What's the point?' This is the point: A move to impeach Donald Trump would go on for months. This would be hours and hours of hearings and televised testimony, all for our couch potato President to take in. He'll be so busy watching and tweeting about it, and just maybe, he'll forget all the other terrible things he wants to do. Impeachment is a good way to distract Donald Trump with the subject he cares about most, which is Donald Trump. Basically, our President is an unruly child throwing a tantrum while we try to eat dinner at a restaurant, and impeachment is an iPad loaded with 'Paw Patrol.' So I say, send in Ryder and his team of pups, and let's see what happens."

Jimmy Kimmel: [On Sean Spicer's performance on 'Dancing With The Stars'] "Somehow 'Dancing With The Stars' found a way to humiliate Sean Spicer more than the President of the United States."

Stephen Colbert: "[Trump] is at fundraisers today in Silicon Valley and Los Angeles. But because he's so unpopular in California, the events were shrouded in secrecy. In fact, attendees at Tuesday's event were not even provided with the address of the lunch. Though, it is easy to find Trump's lunch – just follow the trail of ketchup packets and Filet-o-Fish wrappers."

Stephen Colbert: "Still, the events sold out in a hurry. According to one California Republican, 'They're excited because we've had surrogates like Don Jr. come out. But this is the real thing.' Yeah! The real thing! Hollywood wants to see the special effects that make Trump seem so lifelike."

Stephen Colbert: "Now Trump, of course, is a TV guy. So it's no coincidence that his LA fundraiser is taking place during Emmy week. He is up for outstanding achievement in visual effects for Sharpie on a weather map."

Stephen Colbert: "Now, I can understand going to Los Angeles. He's not popular there, but Hollywood is a thin layer of dirt scattered over a pool of money. Everyone wants to get their drill bit through that crust into that sweet bubblin' cash crude. They're largely liberal, but there's enough money that everyone, no matter how horrible, gets funded. Trump is, let's say, 'The Emoji Movie' of candidates."

Stephen Colbert: "[Trump's] internal polling must be terrible, because he is reaching out to people who want nothing to do with him. And this time, it's not Melania. ... Last night, the President held a rally in a state he lost last time by eight points, New Mexico. ... After four years of Donald Trump throwing Latinos under the bus that he stopped at the border, by saying that illegal and legal immigrants are all coming to kill us, Trump's plan to win is to woo Hispanic voters. Woo, boy. Buena suerte with that, El Trumpo."

Stephen Colbert: "Right now, Trump's approval rating among Hispanics is 25 percent. So, this is like Cruella De Vil trying to woo Sarah McLaughlin."

Stephen Colbert: "Trump must really need los hombres hispanico because he laid it on muy thick ... Always a good sign, asking minorities to identify themselves. (As Trump) 'Okay, who here is Latino? Raise your hands. Whoa. I can't believe you fell for that. Round 'em up, boys!'"

Stephen Colbert: "But Trump wasn't the only one rallying last night. So was Massachusetts Senator...Elizabeth Warren. ... Last night, she held a rally in New York's Washington Square Park, which drew a crowd of 20,000 people! Yeah, 20,000! ... Only 3,000 of which were there to score weed."

Jimmy Fallon: "Well, you guys, last night, the Jets lost to the Browns on Monday night football 23-3, and it was embarrassing and hard to watch, just like Sean Spicer on 'Dancing With The Stars.'"

Jimmy Fallon: "That's right, Sean Spicer made his debut on 'Dancing With The Stars' last night. It was so bad, the judges actually turned their chairs around like 'The Voice.'"

Jimmy Fallon: "A lot of people weren't happy that Spicer was given a spot on 'Dancing With The Stars' due to his role

in the Trump Administration. We got to be careful, or we'll tarnish the great American institution, 'Dancing With The Stars.'"

Jimmy Fallon: "Today, Trump held a fundraiser in California, where he has some of his worst approval ratings. It's bad. When Trump drove by Disneyland, Mickey Mouse said if he had a middle finger, he'd be using it."

Jimmy Fallon: "Last night, Elizabeth Warren held a massive rally right here in New York City. ... That's right, Warren was so popular, the only way police could get everyone to leave was by saying, 'Ladies and gentlemen, please welcome New York City Mayor Bill de Blasio.'"

Jimmy Fallon: "And Warren wasn't the only Democrat in the park. Bernie Sanders was also there on a bench feeding the pigeons, and muttering to himself, 'The top one percent get all the bread crumbs.'"

Seth Meyers: "According to fact checkers, President Trump made at least 26 false statements last night during his rally in New Mexico, and that was just during the sound check."

Seth Meyers: "President Trump watched his former campaign manager Corey Lewandowski's congressional testimony today from aboard Air Force One. And when you're trying to prove you're not a criminal, it doesn't help that your boss is watching from the getaway car."

Seth Meyers: "During an event in South Carolina yesterday, Republican presidential challenger Mark Sanford held a mock debate against a cardboard cutout of President Trump. You could tell the cutout wasn't the real Trump, because it made some good points."

Seth Meyers: "Following her rally in New York last night, Sen. Elizabeth Warren spent four hours taking selfies with supporters. Meanwhile, Bernie took one selfie that lasted four hours because the camera was accidentally set to video."

James Corden: [On Trump saying that Steve Cortes looks "like a WASP"] "President Trump had another one of his giant rallies last night, this time in New Mexico as an outreach to Hispanic voters. And at the rally, Trump referenced CNN contributor and Trump supporter Steve Cortes, who was just offstage. ... So, in Trump's mind, the highest compliment he can give is, 'I like you, Steve. You could pass for a white guy!'"

James Corden: "Trump on his absolute best behavior still talks about race like it's fantasy football. Trump asked Steve Cortes, 'Who do you like more, the country or the Hispanics?' Coincidentally, that's also the first and only question asked in a White House job interview."

James Corden: "In other White House news, for the first time in history, the Secret Service has now formally requested – and we're not making this up – they've formally requested jet skis. They say they need them because the Trump family spends a lot of time vacationing out on the water. ... The Secret Service said they need the jet skis to protect the first family. You know, from rogue Frisbees or any other dangers commonly found in a '90s beer commercial."

James Corden: "This is true. The Secret Service only asked for two jet skis. They didn't want to blow their whole budget because they're saving up to buy a monster truck."

NATIONAL NEWS

Trump: California Cities "Destroying Themselves" With Homelessness. President Trump's comments about homelessness in California, made before his arrival, receive more national media attention than his fundraising events in the state. The San Francisco Chronicle (9/17, Wildermuth, 2.67M) reports Trump "made his first visit to the Bay Area on Tuesday since taking office, raising money, dodging protesters and, shortly before landing, warning that San Francisco and other California cities were 'destroying themselves' with homelessness." On Air Force One en route to California, the President told reporters, "Hundreds and hundreds of tents and people living at the entrance to their office building. And they want to leave. And the people of San Francisco are fed up, and the people of Los Angeles are fed up. And we're looking at it, and we'll be doing something about it." The President "didn't venture what that might be, other than to say he was looking into the creation of an 'individual task force' and talking with [HUD Secretary Carson] 'in terms of the housing element.'"

The Los Angeles Times (9/17, Oreskes, Rust, Shalby, Cosgrove, 4.64M) reports, "In recent months, Trump has used the issue of homelessness to bash" California. State officials "have been wary of the Trump administration's intentions, concerned that the president wants to use homelessness and urban ills as a wedge for the 2020 campaign. But they have said that they are willing to work with Trump." USA Today (9/17, Collins, Fritze, 10.31M) reports Trump "previously has described California's homeless problem as 'disgusting' and a 'disgrace to our country.'" USA Today says Trump "routinely slams the policies" of the "overwhelmingly Democratic" state.

The New York Times (9/17, Dougherty, 18.61M) reports, "Numerous protesters and politicians said they found Mr. Trump's sudden interest in homelessness to be disingenuous and an example of the administration trying to score political points at the state's expense instead of actually grappling with a humanitarian crisis that has become the

driving political issue in state and local politics." The Washington Post (9/17, Dazio, 14.2M) reports Trump "began a California visit on Tuesday, saying he will do 'something' about homelessness but offering no specifics beyond the mention of creating a task force." Los Angeles Mayor Eric Garcetti "said he would welcome Trump's help to end homelessness if he contributed federal dollars or property that could be converted into shelters."

The San Francisco Chronicle (9/17, Fagan, 2.67M) – writing that "he came, he saw, he offered nothing specific" – reports Carson "paid a quick visit to a public housing project in Potrero Hill, dodged an invitation to meet with the mayor, and left – all in the space of about an hour." His "purpose in visiting the housing project was to 'listen' and gather facts, Carson said." The San Francisco Examiner (9/17, Waxmann, 438K) reports Carson "echoed calls by a White House committee to deregulate the housing market and increase policing." Carson said, "Evidence shows us quite clearly that the places that have the most regulation also have the highest prices and the most homelessness. Therefore it would seem only logical to attack those things that seem to be driving the issues."

Rep. Barbara Lee (D-CA) tweeted, "If Trump is serious about addressing homelessness, he needs to quit the cuts to programs that keep people housed and invest in the things we know help families keep a roof over their heads."

Ex-Rep. Beto O'Rourke (D-TX) tweeted, "This is classic Trump. He's going to terrorize homeless Americans because he thinks they can't fight back. They deserve shelter. They deserve affordable housing. They deserve mental health care. And most of all they deserve dignity."

Protesters Assemble Near Trump Fundraising Events. The AP (9/18, Slodysko, Slodysko, Freking, 12.82M) says Trump "rarely passes up the chance to throw a sharp elbow at left-leaning California, but he showed Tuesday he's more than happy to cash in there with a lunch-dinner-breakfast-lunch fundraising blitz expected to scoop up \$15 million from wealthy Republicans in two days." The East Bay Times (9/17, Woolfolk, 63K) reports Trump appeared at "a high-dollar fundraiser at the home of a former technology executive in the hills above Palo Alto...with tickets ranging from \$1,000 to \$100,000." The President later attended "other fundraising events in Los Angeles and San Diego."

The San Francisco Chronicle (9/17, Serrano, 2.67M) reports protesters turned out near the home of Sun Microsystems co-founder Scott McNealy, host of the Palo Alto event. The San Francisco Chronicle (9/17, Garofoli, 2.67M) says McNealy "is one of the few tech titans who have consistently supported the president." Bay City News Service (9/17, Service, 80K) reports, "Protesters with activist groups like the Backbone Campaign and Raging Grannies went alongside a road in Portola Valley with colorful inflated balloon versions of Trump to look like a baby and a chicken."

The activists also were handing out stickers calling for Trump's impeachment."

KTVU-TV San Francisco (9/17, 6:03 p.m. PDT, 41K) reported, "Protesters gathered, some holding signs and banners that expressed their anger." KABC-TV Los Angeles (9/17, 6:00 p.m. PDT, 246K) reported there were also demonstrators near the President's Beverly Hills fundraiser at the home of real estate developer Jeffrey Palmer. KCBS-TV Los Angeles (9/17, 6:00 p.m. PDT, 109K) also focused its report largely on the demonstrations.

EPA Expected To Revoke California's Authority To Set Stricter Fuel Efficiency Standards. Reuters (9/17, Shepardson) reports the Trump Administration "will announce as early as Wednesday it is revoking California's authority to set its own greenhouse gas and vehicle fuel efficiency standards and barring all states from setting such rules, two auto industry officials said on Tuesday." The Los Angeles Times (9/17, Phillips, 4.64M) reports the President "is expected on Wednesday to revoke a decades-old rule that empowers California to set tougher car pollution standards than those required by the federal government – putting the state and the [EPA] on a path to years of fighting in court."

The San Jose Mercury News (9/17, Rogers, 456K) reports EPA officials "declined to comment," but EPA Administrator Wheeler "told the National Automobile Manufacturers Association Tuesday: 'We will be moving forward with one national standard very soon.'" The Washington Post (9/17, Eilperin, Dennis, 14.2M) says the move "is likely to be unpopular nationwide and in California, with Americans widely supportive of stricter fuel efficiency standards. A Washington Post-Kaiser Family Foundation poll released Friday found 66 percent of Americans oppose Trump's plan to freeze fuel efficiency standards rather than enforce the Obama administration's targets for 2025."

The Sacramento Bee (9/17, Kasler, Wilner, 567K) reports Gov. Gavin Newsom (D) said California will "fight this latest attempt and defend our clean car standards." Newsom tweeted, "Fact is, CA's outperforming the federal government: Running record surpluses while Trump runs record deficits. Meeting our climate goals while expanding our economy. We're the progressive answer to a transgressive President – and it's driving him mad." The New York Times (9/17, Davenport, 18.61M) reports California Attorney General Xavier Becerra (D) "wrote in an email: 'California will continue its advance toward a cleaner future. We're prepared to defend the standards that make that promise a reality.'"

Politico (9/17, Guillén, 4.29M) says it "first reported earlier this month that the Trump administration planned to sever and advance the portion of its auto emissions rollback targeting California from the broader, more technical rulemaking setting new national standards for model year 2021 vehicles and beyond." The Hill (9/17, Green, 2.98M) also has a report.

Rep. Brad Sherman (D-CA) tweeted in response to the plan, "Outrageous. A blow to our environment. A blow to American energy independence. A boon to those who benefit from higher oil prices, like #Venezuela & #Iran."

Fed Intervenes To Keep Rates From Rising Above Target For First Time Since 2008.

The New York Times (9/17, Smialek, 18.61M) reports that the Federal Reserve on Tuesday "had to step into financial markets...to keep interest rates from rising above its target, the first time the central bank has had to carry out this type of 'market operation' since the global financial crisis." The Times says the Federal Reserve Bank of New York "had to spring into action to keep the effective fed funds rate in line after it rose to the very top of the Fed's 2 to 2.25 percent range." According to the Times, "Tuesday's intervention is symbolically important. The central bank decided just this year to keep its balance sheet large enough that it can set its policy rate without active market operations. But this episode suggests that it may not have kept its holdings big enough for that approach to work amid more extreme market conditions."

The Wall Street Journal (9/17, A1, Timiraos, Kruger, Subscription Publication, 7.57M) reports on its front page that the Fed on Tuesday morning injected \$53 billion into the banking system through transactions known as repurchase agreements. According to the Journal, the factors behind the elevated rates were related to a scarcity of funds for banks, due to rising government deficits and the Fed's move to reduce its securities holdings in recent years.

CNN Business (9/17, Egan, 21.56M) reports on its website that "the NY Fed announced plans late Tuesday to hold another repurchase agreement operation on Wednesday that would aim to repurchase up to an additional \$75 billion." According to the article, "the episode demonstrates evidence of emerging strains in financial markets and raises concern that the Federal Reserve could be losing its grip on short-term rates." The article adds that "it's unclear what exactly is causing the stress in the overnight market, or how long it will last."

AFP (9/17) and Bloomberg (9/17, McCormick, Harris, 4.73M), among other news outlets, also cover the Fed's intervention.

Fed Likely To Lower Interest Rates On Wednesday With Economy Facing Risks.

USA Today (9/17, Davidson, 10.31M) reports, "Despite firming inflation and easing trade tensions, the Federal Reserve is likely to lower interest rates Wednesday for the second time in less than two months and pave the way for another likely cut later this year to head off persistent risks from overseas." However, "with economic reports decidedly mixed in recent weeks, Fed Chairman Jerome Powell must bridge continued sharp divisions among Fed policymakers, many of whom favored no rate decrease

in July." USA Today adds that "Powell also must endure continued taunts" from President Trump, "who has called for sharper rate cuts and even negative interest rates to help the US keep pace with Europe."

Manufacturing Production Rebounds. Reuters (9/17, Mutikani) reports "US manufacturing output increased solidly in August, boosted by a surge in the production of machinery and other goods, but the outlook for factories remains weak amid rising headwinds from trade tensions and slowing global economies." The "fairly upbeat report from the Federal Reserve on Tuesday came as officials from the US central bank gathered for a two-day policy meeting." Reuters adds "manufacturing production rose 0.5% last month after an unrevised 0.4% drop in July, the Fed said. Economists polled by Reuters had forecast manufacturing output rising 0.2% in August."

Senators Urge Antitrust Regulators To Strenuously Investigate Big Tech. The New York Times (9/17, McCabe, 18.61M) reports, "Senators pressed top antitrust regulators on Tuesday to aggressively investigate the power of the country's biggest tech companies, with some lawmakers questioning whether the officials had the will or resources to take on Silicon Valley's richest businesses." However, "the regulators – Joe Simons, the chairman of the trade commission, and Makan Delrahim, the top antitrust official at the Justice Department – offered few details about their inquiries into the industry," frustrating some lawmakers. Simons and Delrahim have "divided up responsibility for handling antitrust complaints about the companies," but "the accord between the agencies appears tenuous," and lawmakers also "pressed the regulators on Tuesday on reports that they were at odds over the investigations."

Trump Says US, Japan Have Reached A Trade Deal. The Washington Post (9/17, 14.2M) reports that President Trump said Tuesday that he has "reached a trade deal with Japan but provided no details of its terms, including whether he had agreed to rule out imposing tariffs on Japanese automobiles." In a statement released by the White House, Trump said, "I am pleased to report that my Administration has reached an initial trade agreement regarding tariff barriers...with Japan and I intend to enter into the agreement in the coming weeks." The Post adds that Trump is "expected to meet" Japanese Prime Minister Shinzo Abe "later this month at the annual United Nations General Assembly session," and White House officials "had been hopeful that they could announce major progress regarding the talks during the meeting."

Administration Moves To Announce Trade Deals With Japan, India. The New York Times (9/17, Swanson,

Dooley, Goel, 18.61M) reports that the Administration "is racing to announce limited trade deals with Japan and India before the end of the month, as President Trump tries to score some wins amid a trade fight with China." The effort is "aimed at helping Mr. Trump overcome concerns about his trade approach before the 2020 election and prove to voters that he is delivering on a key promise to negotiate bilateral trade deals in America's favor." In addition, Trump "wants to calm the concerns of struggling farmers, who have been largely cut off from foreign markets like China in retaliation for the president's trade war."

Proposed Rules Would Give Greater Scrutiny To Foreign Investment In US Tech, Infrastructure, Data. The Wall Street Journal (9/17, Ferek, Subscription Publication, 7.57M) reports the Administration on Tuesday released proposed rules that would subject foreign investors seeking to invest in US businesses involved in technology, infrastructure, and data to more stringent national security scrutiny.

The New York Times (9/17, Rappeport, 18.61M) says the new rules "would add teeth to a 2018 law, the Foreign Investment Risk Review Modernization Act, that expanded the powers of a government panel to block transactions on national security grounds." They "would give the Committee on Foreign Investment in the United States, or CFIUS, greater power to stop foreign investment in areas the United States deems protected. While the rules would apply to any foreign investment, the effort is primarily aimed at preventing China from gaining access to sensitive American technology and other valuable assets."

McConnell: Senate In "Holding Pattern" On Guns Until Trump Expresses Preferences. The Washington Times (9/17, Sherfinski, 492K) reports Senate Majority Leader McConnell on Tuesday "said lawmakers are in a 'holding pattern' on gun-related legislation until President Trump clearly articulates what kind of package he would support." McConnell "expressed an interest in acting in the wake of the recent shootings in Texas and Ohio, but reiterated that it will take support from the Democrat-controlled House, the Republican-controlled Senate, and Mr. Trump to get anything signed into law." Said McConnell, "I know I'm the majority leader, but I'm telling you, I want to know what the President supports – it's not unimportant to my members. ... Until we get that kind of guidance, we're in a holding pattern, so to speak."

Teens Arrested For Three High School Shooting Plots In California, Oklahoma. NBC Nightly News (9/17, story 6, 1:21, Holt, 5.96M) reported police in California and Oklahoma are "crediting tips in the public

with possibly stopping school shootings in those states." NBC's Pete Williams said, "In southeastern Oklahoma, 18-year-old Alexis Wilson is charged tonight with making a terrorist threat, accused of telling a co-worker she wanted to shoot up McAlester High School, which she once attended." He added, "In Desert Hot Springs, California, three 14-year-olds, two boys and a girl, are charged with threatening on social media to shoot their high school."

On ABC World News Tonight (9/17, story 2, 1:55, Muir, 6.62M), Steve Osunsami said that "a 16-year-old from Fresno high school in California" is also under arrest "after a post he made to Instagram."

Some Of Trump's Hurricane Briefings Do Not Include Meteorologists. The Washington Post (9/17, Freedman, Samenow, 14.2M) reports that President Trump's "inaccurate assertion" that Hurricane Dorian would impact Alabama "exposed a flaw in the White House's storm briefing process – some of those meetings did not include meteorologists," despite the fact that Trump "has an advantage compared to his predecessors: the presence of a highly qualified meteorologist on his White House staff. Kelvin Droegemeier, a longtime research meteorologist, serves as the head of the White House Office of Science and Technology Policy (OSTP)." But, Droegemeier "did not attend formal hurricane briefings provided to Trump in the run-up to Hurricane Dorian's devastating strike in the northwest Bahamas and eventual landfall in North Carolina, according to a senior administration official."

Tropical Storm Imelda Forms, Posing Risk Of Flash Floods In Texas, Louisiana. The CBS Evening News (9/17, lead story, 1:14, O'Donnell, 4.34M) reported "a tropical storm is hitting" Houston Tuesday night. Imelda "intensified rapidly, targeting the Houston area with life-threatening flash floods." On NBC Nightly News (9/17, lead story, 0:55, Holt, 5.96M), Al Roker reported that "the flash flood watches extend into Louisiana."

Hurricane Humberto Gaining Strength. ABC World News Tonight (9/17, lead story, 1:34, Muir, 6.62M) reported Hurricane Humberto is "gaining strength...with concern over dangerous rip currents." ABC chief meteorologist Ginger Zee said Hurricane Humberto "should be a major hurricane by [Wednesday]."

DeVos Visits Nontraditional School In Cleveland. The Cleveland Plain Dealer (9/17, Richardson, 895K) reports that "as part of her back to school tour of abstract learning facilities," Education Secretary DeVos was in Cleveland Tuesday where she visited Edwins Leadership and Restaurant Institute, where "formerly incarcerated learn the ropes of fine dining and French cuisine." DeVos said,

"This is just a terrific example of the opportunity for education and serving in a way that some people gravitate to just like a duck to water. ... I have been tangentially involved in the restaurant business and I know that people who love to cook love to cook. When they find that passion and can develop that to the highest level of excellence, what could be better than that?" DeVos "did not say whether she thought there was a place for the federal government to assist a school like Edwins, though she listed making PELL grants or student loans available to entrants as a possible means for federal assistance."

Trump Names Five Finalists For National Security Adviser Post. Politico (9/17, Forgey, 4.29M) reports the President yesterday "revealed his top five candidates to replace former national security adviser John Bolton." Politico adds that "speaking to reporters aboard Air Force One while en route to California, Trump said he is considering Fred Fleitz, Lisa Gordon-Haggerty, Keith Kellogg, Robert O'Brien and Ricky Waddell to lead his White House's National Security Council." The New York Times (9/17, Baker, 18.61M) says that "in naming the five, Mr. Trump seemed to be ruling out several others who had been considered or proposed to him, including two top aides to" Secretary of State Pompeo – "Stephen E. Biegun, the special envoy for North Korea, and Brian H. Hook, the special envoy for Iran. Another who had been mentioned but was not included on the president's list was Richard Grenell, the ambassador to Germany and a conservative firebrand." The Washington Post (9/17, Gearan, 14.2M) reports "Grenell attended a dinner with Trump on Saturday amid speculation that he was in the running for Bolton's job," but "a senior administration official said...that Grenell was in Washington because he 'has been in discussions for weeks about another role the president wants him to play.'"

The New York Post (9/17, Moore, 4.57M) recounts "Trump praised Kellogg, saying 'he's been with me from the beginning. He's great,'" and "called O'Brien 'fantastic' and said he likes Waddell 'a lot.'" The Hill (9/17, Chalfant, 2.98M) reports "it's unclear when Trump will name his choice." Reuters (9/17, Mason), the Washington Examiner (9/17, Nelson, 448K), and the Daily Caller (9/17, 716K), among other news outlets, also report the story.

Senate Panel To Vote On Scalia Nomination September 24. The Washington Examiner (9/17, Higgins, 448K) reports Senate Health, Education, Labor, and Pensions Chairman Lamar Alexander "announced Tuesday that the panel will vote on President Trump's pick to head the Labor Department, private sector lawyer Eugene Scalia, on Sept. 24, less than one week after his first nomination hearing." Scalia "has been criticized by Democrats and

organized labor as too close to big business. The quick pace of the nomination and vote suggest the administration and its GOP allies don't want to give critics a chance to build up opposition to the nominee."

White House Fires DHS General Counsel. The New York Times (9/17, Kanno-Youngs, Haberman, 18.61M) reports, "The White House on Tuesday fired John Mitnick, the general counsel for the Department of Homeland Security, after months of shake-up at an agency responsible for carrying out President Trump's immigration agenda." An Administration official "said Tuesday evening that Chad Mizelle, an associate counsel to the president, would replace Mr. Mitnick." However, "a Department of Homeland Security official said later that Joseph B. Maher, the department's principal deputy general counsel, would be taking over."

Administration Proposes New Rules To Streamline Disciplinary Process For Federal Employees. The Washington Post (9/17, Yoder, 14.2M) reports federal agencies would have more latitude "in disciplining their employees, and the employees would be guaranteed only the minimum protections required by law, under rules the Trump administration proposed Tuesday." The rules would discard "many of the practices agencies have followed in disciplining employees while urging them to move as fast as the law allows." According to the article, "most of the changes would put in place the parts of a May 2018 executive order from President Trump that are not affected by a court injunction blocking portions of that order and two others issued at the same time."

Media Analyses: Lewandowski Testimony Enrages Democrats. Media reports and analyses, including segments on all three network newscasts, cast Democrats on the House Judiciary Committee as infuriated by the testimony of Corey Lewandowski. Politico (9/17, Desiderio, Cheney, 4.29M) says, for example, that Lewandowski "sent Democrats into a rage...as he swatted down dozens of questions about potential obstruction of justice by the president." Politico adds that "two White House lawyers were seated behind an indignant Lewandowski as he repeatedly deferred to their demands to sharply restrict his testimony." The AP (9/17, Jalonick) reports Lewandowski, moreover, "made clear his dislike for the House majority in the opening statement, calling them petty and asserting that investigations of the president were conducted by 'Trump haters.'"

The Daily Caller (9/17, 716K) quotes from Lewandowski's opening statement: "In conclusion, and it's sad to say, this country has spent over three years and 40 million taxpayer dollars on these investigations, and it's now

clear that the investigation was populated by many Trump haters who had their own agenda – to take down a duly elected president of the United States." USA Today (9/17, Jansen, 10.31M) reports Lewandowski also "said...that it was 'very unfair' that committee Democrats unilaterally changed the rules a week ago to make the hearing part of an impeachment proceeding." Said Lewandowski, "We as a nation would be better served if elected officials like you concentrated your efforts to combat the true crises facing our country as opposed to going down rabbit holes like this hearing." President Trump wrote on Twitter, "Such a beautiful Opening Statement by Corey Lewandowski! Thank you Corey!"

Fox News (9/17, Pappas, 27.59M) recounts on its website that Lewandowski "declined to play along with certain questions." Rep. Hakeem Jeffries (D-NY), for example, "asked Lewandowski if he was Trump's 'hitman, the bag man, the lookout, or all of the above?'" Lewandowski replied, "I think I'm the good looking man, actually." The New York Post (9/17, Schwab, 4.57M) reports, meanwhile, that at one point, Chairman Jerrold Nadler "said Lewandowski could go ahead and answer a question" from Rep. Sheila Jackson-Lee (D-TX) "even though her time had elapsed." Said Lewandowski, "I don't believe there was a question, Congressman. ... Just a rant." Lewandowski also "poked fun at" Rep. Eric Swalwell (D-CA) – "who already dropped out of the 2020 race – by calling him 'President Swalwell.'" The San Francisco Chronicle (9/17, Ting, 2.67M) indicates that Swalwell "tried to make Lewandowski read his own notes he submitted to special counsel Robert Mueller regarding a meeting with...Trump on July 19, 2017." Lewandowski "refused to read it," and said, "President Swalwell, I'm very happy with what I've written but you're welcome to read it if you like."

Writing for the CNN (9/17, 83.16M) website, Chris Cillizza said that "within the first five minutes of...Lewandowski's 'testimony'...it became crystal clear what...Trump's former campaign manager was up to: trolling to please his old boss." Kaitlan Collins similarly said on CNN's Situation Room (9/17, 734K) that Lewandowski "was performing for an audience of one:" Trump, and Gloria Borger said on CNN's Situation Room (9/17, 734K) that Lewandowski "did what he wanted to do, which was to look like he was stonewalling Congress, to play to the President – and to play to people who might one day get the chance to vote for him in the state of New Hampshire." Under the headline "Corey Lewandowski Debuts His Senate Campaign Theme: Unbridled Nastiness," meanwhile, Dana Milbank writes in the Washington Post (9/17, 14.2M) that Lewandowski's "combative performance brought the House Judiciary Committee, never a harmonious assembly, to a new level of acrimony. ... Back and forth lawmakers and witness went: Coverup. Socialists. Obstruction. Lie. Contempt. Fake

news. Impeachment. Joe Biden's record player. Trump's Sharpie."

The Washington Post (9/17, 14.2M) says "it was Lewandowski's attitude that most infuriated panel Democrats – even prompting a contempt threat" from Rep. David Cicilline (D-RI). The Post reports that "time after time, Lewandowski tried to show that this was his performance and he was the man in control, even tweeting from the room about his possible 2020 bid for the Senate and lecturing a congressman for saying the tooth fairy wasn't real. 'New website just launched to help a potential senate run. Sign up now!' he wrote during a panel break, a reference to his potential challenge" to Sen. Jeanne Shaheen (D-NH). NBC Nightly News (9/17, story 7, 0:30, Holt, 5.96M), the CBS Evening News (9/17, story 8, 1:35, O'Donnell, 4.34M), and ABC World News Tonight (9/17, story 6, 1:35, Muir, 6.62M) all referred to "fireworks" on Capitol Hill, and ABC also reported that "during a break from the hearing, Lewandowski took time to promote a PAC, encouraging him to make a possible Senate run in New Hampshire."

NPR (9/17, Ewing, 3.12M) reports "Democrats were frustrated at what they called stonewalling," while "Republicans were angry about what they called a waste of time." Reuters (9/17, Morgan, Wolfe) says Lewandowski, "vigorously defended his former boss and lashed out at Democrats but repeatedly dodged their questions during a contentious hearing before a...panel considering whether to impeach Trump." The AP (9/17) indicates he did "confirm" that Trump "asked him to urge Jeff Sessions to reverse himself and oversee the Russia investigation." Lewandowski said he "never delivered that message, but he told the House Judiciary Committee that Trump didn't ask him to break the law." The AP reports that when "asked why, according to the Mueller report, he never delivered the message to Sessions as instructed, Lewandowski answered that he had taken his kids to the beach." The New York Times (9/17, Haberman, Fandos, 18.61M) covers Lewandowski's appearance under the headline "Lewandowski Confirms Trump Asked Him To Help Curtail Mueller Inquiry," while the Washington Times (9/17, Mordock, 492K) titles its story "Corey Lewandowski Hearing Erupts In Chaos Over Mueller Report." The Los Angeles Times (9/17, Megerian, 4.64M), Bloomberg (9/17, House, 4.73M), The Hill (9/17, Beavers, 2.98M), CQ Roll Call (9/17, Ruger, 154K) and the Wall Street Journal (9/17, Ballhaus, Hughes, Subscription Publication, 7.57M), among other news outlets, also report the story.

Lewandowski said on Fox News' The Story (9/17), "I think I reiterated what the American people already knew: There was no collusion and obstruction. The Mueller report was very clear about that. And what we know, the far left wing of the Democratic party has to have these hearings to protect themselves in their congressional districts from further-left progressives who want to take them out in their primary

elections. This is all politics, and the truth is it's a disservice to the American people." Lewandowski added, "I've spent more than 20, maybe 25 hours, answering questions before the House Intelligence Committee, the Senate Intelligence Committee, the Special Counsel's office. I have nothing to hide, because we never committed any crimes in the campaign. We never colluded with anyone, which is exactly what the Mueller report says."

House Judiciary Committee ranking member Rep. Doug Collins (R-GA) said on Fox News' The Story (9/17) that Nadler "has turned this into a press release committee. All they want to do is have cameras show up, the press show up, and they will throw anything they can at the President to try to tear him down. Anything to try and tear him down. They have become literally the political arm of the DCCC."

Rep. Jackie Speier (D-CA) said CNN's The Lead (9/17, 649K), "I think you have to look at Mr. Lewandowski as an adverse witness. He had no interest in complying with this actual subpoena outside of showing up. He intended to obstruct justice once again, frankly, by not being willing to give answers to questions by the Democrats. I think if I were Mr. Nadler right now, I would be slapping Mr. Lewandowski with an inherent contempt order and calling him in front of the House of Representatives and fining him."

Rep. Steve Cohen (D-TN) said on CNN's Situation Room (9/17, 673K), "I think we could hold him in contempt of Congress for refusal to answer questions. I don't know that we will. I think we should and I think we should have done it before. I suggested it months and months and months ago that we should have done it with Attorney General Barr for refusing to show up and others. We need to get tougher because the Republicans play tough" because "they know that there is information to be gained from seeing information in the grand jury testimony and from documents that we have subpoenaed and witnesses we have subpoenaed and they're trying to stop it as much as they can. Trump knows what's in there, and Trump is scared to death of the truth coming out."

Media Analyses: Lewandowski May Ride House Hearing Performance Into NH Senate Race. The Washington Times (9/17, McLaughlin, 492K) reports Lewandowski, who is considering a Republican bid to unseat Shaheen, "has been consuming most of the oxygen in the" GOP primary – "and he's not even a candidate yet." The Times says that Lewandowski's "loyalty to Mr. Trump has earned him a rarefied status among the president's followers and given him a national profile that analysis say could excite voters and help him rake in tons of money" if he runs. The Times adds, "During a break in his contentious hearing before the House Judiciary Committee, Mr. Lewandowski tweeted out the link to a new website aimed at boosting his Senate hopes. It prominently features a Mr. Trump quote praising Mr. Lewandowski. Michael Dennehy, a New Hampshire-based

Republican strategist, said Mr. Lewandowski 'truly is a mini-me of Donald Trump.'"

CQ Roll Call (9/17, Connolly, 154K) reports, "Frustrating the Democrats and proving loyalty to...Trump: That's just good politics for a Republican." CQ Roll Call says Lewandowski seemed "to be banking on [that] Tuesday as he testified before the House Judiciary Committee and continued to tease a possible bid for Senate. ... Not only did fellow Republicans give him ample opportunities to praise" Trump, but Lewandowski also "used Twitter to pique interest in the hearing before it started, and during a break sent out a link to a potential campaign website." CQ Roll Call adds that with three other candidates already in the GOP Senate primary, "Trump's base could be the key to coming out first in that crowd." Said Dennehy, "Whoever is more closely aligned to Trump will win the primary. If Trump endorses Lewandowski – it's game over and Corey wins in a landslide."

The Hill (9/17, Greenwood, 2.98M) quotes Lewandowski as tweeting during a break in yesterday's hearing, "New website just launched to help a potential senate run. Sign up now!" The Daily Beast (9/17, Brodey, Trudo, 1.39M) reports that "Tuesday's high-profile hearing was essentially a coming-out party for Lewandowski's long-teased, but still unannounced campaign for US Senate in New Hampshire: he talked up his 'blue collar' roots and service to...Trump while effusively praising his former boss and gleefully trolling his Democratic questioners."

NYTimes Decries Democrats' Conflicting Messages On Impeachment. In an editorial, the New York Times (9/17, 18.61M) says that while the House Judiciary Committee "has begun an inquiry to determine whether to recommend the impeachment of President Trump," there is "tremendous confusion about what the Judiciary Committee is up to – largely because of conflicting signals from House Democrats." House Speaker Pelosi "paint[s] the committee's work as garden-variety oversight," and "as a result, even Democratic lawmakers don't seem to know whether they are engaged in an impeachment inquiry." The Times says the "contradictory statements make Democrats look divided and conflicted, complicating efforts to build public confidence in their oversight powers," and calls on Democrat leaders to "try to find a way forward that, at the very least, doesn't leave members contradicting one another and further embolden Mr. Trump."

DOJ IG's Findings Are Driving Force Behind Possible Criminal Charges For McCabe. The Washington Times (9/17, A1, Scarborough, 492K) reports that Justice Department Inspector General Michael Horowitz's report "is the driving force for possible criminal charges against former FBI Deputy Director Andrew McCabe,

as his attorneys and the department square off in a legal and media showdown." The IG found that McCabe "lied to fellow agents and cast blame on colleagues for his orchestrated press leak." McCabe "rejects the inspector general's conclusions," and he "filed suit last month in US District Court alleging that the Trump Justice Department illegally fired him in retaliation for pursuing the Russia investigation." The Times story goes on to detail Horowitz's conclusions "that resulted in [McCabe's] firing in March 2018, a few days short of full retirement, and prompted US Attorney Jessie K. Liu to weigh criminal charges."

Comey Says He Is "Highly Confident" He Won't Be Indicted. The Washington Examiner (9/17, Dunleavy, 448K) reports that former FBI Director James Comey said Monday that he does not think he will be indicted. At an appearance with "Josh Campbell, his former special assistant at the FBI and now a CNN legal analyst, to discuss Campbell's new book Crossfire Hurricane at George Washington University," Comey said, "I keep seeing that I'm going to be indicted, which they said over and over again for the last two years. I'm highly confident that's not true. So then they'll just move on, making other stuff up after that peters out."

Schiff: Acting DNI Has Refused To Hand Over Whistleblower Complaint. The Washington Post (9/17, Demirjian, 14.2M) reports Acting DNI Joseph Maguire will "not comply with a House Intelligence Committee subpoena ordering him to provide the panel with a whistleblower's report of 'serious misconduct,' escalating a standoff with the panel's chairman over a complaint he believes could involve the White House." House Intelligence Chairman Adam Schiff said, "We're determined to make sure that the whistleblower is able to provide his complaint to Congress, or her complaint to Congress, and that this urgent matter is addressed. [Maguire] has yet to provide the complaint in response to the Committee's subpoena, so I expect him to appear on Thursday, under subpoena if necessary."

Politico (9/17, Cheney, 4.29M) reports Schiff "warned the agency might be acting to conceal high-level wrongdoing by President Donald Trump or his immediate advisers." However, DNI general counsel Jason Klitenic "insisted in a letter to Schiff on Tuesday that Maguire had followed the letter of the law in blocking the transmission of the complaint to Congress." Klitenic also called it "premature" for Maguire to appear on Thursday before Congress, "saying Maguire wouldn't be available on short notice and that he's still considering the appropriate response to the committee's demands."

The New York Times (9/17, Barnes, Fandos, 18.61M) reports, "Still, a senior intelligence official said, Mr. Maguire wants to find a way to work with the committee and try to accommodate Mr. Schiff's requests while still ensuring the whistle-blower's identity is protected."

Blasey Ford Friend Says She Doubts Her Accusation Against Kavanaugh. Breitbart (9/17, Furr, 673K) reports that according to a new book written by New York Times reporters Robin Pogrebin and Kate Kelly, titled "The Education of Brett Kavanaugh: An Investigation," Leland Keyser, a friend of Christine Blasey Ford, who claims she was sexually assaulted by Supreme Court Justice Brett Kavanaugh in 1982, said the story of the alleged assault "didn't make any sense" and that "she was threatened with a smear campaign if she did not support it." CBS' Jan Crawford reported Monday that Keyser claimed "Ford's allies pressured her" to support Ford's accusation and that she was threatened with a "smear campaign" if she did not. Crawford tweeted Monday night, "We report tonight the real bombshell: Christine Ford's close HS friend (who Ford says was at the party when Kavanaugh allegedly assaulted her) said Ford's story is not believable and told the FBI Ford's allies pressured her, threatened her with a smear campaign to say otherwise" The New York Post (9/17, Moore, 4.57M) also reports on Keyser's comments.

Pence: Calls For Kavanaugh's Impeachment Are A "Disgrace." The Federalist (9/17, Justice, 126K) reports Vice President Pence said that calls from Democratic presidential candidates for Kavanaugh to be impeached are a "disgrace." In remarks at the Heritage Foundation, Pence said, "The Democrats and their allies in the media are obviously getting desperate. ... This week, they've taken to smearing a sitting justice on the Supreme Court of the United States with discredited allegations. The calls by Democratic candidates for the president to remove Justice Kavanaugh from the court are a disgrace and nothing short of an attack on our independent judiciary." Pence continued, "Justice Brett Kavanaugh is a good and decent man. ... He is a principled jurist and a credit to the highest court in the land, and these attacks on Justice Kavanaugh must stop."

Senate Judiciary Chairman Lindsey Graham said on Fox News' Hannity (9/17, 535K), "It is not really news that the New York Times did a sloppy job reporting about Trump and Kavanaugh because they are so biased, but what is news to me is that two United States Senators running for president have called for Kavanaugh's impeachment based on an article in the New York Times that is bogus. And a member of the house has introduced impeachment resolution of Judge Kavanaugh based on an erroneous, scurrilous New York Times story. So here is what I want you to know, any impeachment of Judge Kavanaugh based on the New York

Times story is dead on arrival in the Senate. Any impeachment of President Trump based on the Mueller report is dead on arrival in the United States Senate."

NYTimes Reporters Say Editors Removed Key Information From Kavanaugh Story. Politico (9/17, Calderone, 4.29M) reports that Pogrebin and Kelly, who revealed the new allegation against Kavanaugh "blamed [the New York Times'] editors for a critical piece of information not appearing in their original story." In an interview with MSNBC's Last Word "they said...that they wrote in the draft of their Sunday Review piece that a woman who Kavanaugh was said to have exposed himself to while a student at Yale had told others she had no recollection of the alleged incident," but their editors "removed the reference." Said Pogrebin, "It was just sort of...in the haste of the editing process."

The Washington Free Beacon (9/17, Piro, 78K) reports that on ABC's The View, Pogrebin "said the controversial initial tweet promoting" the story was a "misworded tweet" and "that she did not intend for it to be published." Pogrebin "excused the tweet...by saying reporters are asked to draft tweets to go with their articles." She said the draft tweets "don't always get used, they don't always get sent out, they often don't."

Trump: NYTimes Has Become A "Sad Joke" Around The World. In a tweet Tuesday morning, President Trump called the Times a "journalistic disaster" that "has become a sad joke" around the world. Trump wrote, "The New York Times is at its lowest point in its long and storied history. Not only is it losing a lot of money, but it is a journalistic disaster, being laughed at even in the most liberal of enclaves. It has become a very sad joke all over the World. Witch Hunt hurt them...'That story (Kavanaugh) is nowhere near the standard that should be met in publishing a story.' @brithume @FoxNews"

Tuesday evening, Trump tweeted, "The New York Times is now blaming an editor for the horrible mistake they made in trying to destroy or influence Justice Brett Kavanaugh. It wasn't the editor, the Times knew everything. They are sick and desperate, losing in so many ways!"

Trump's tweet Tuesday morning referred to comments by Brit Hume on Fox News Special Report (9/16, 1.53M) Monday evening. Hume made a similar argument on Fox News' Tucker Carlson Tonight (9/17) Tuesday evening. Hume said, "This is a story that should never have gotten anywhere near print. This is nowhere near publishable. It's not even remotely close."

The Washington Examiner (9/17, Ferrechio, 448K) reports that Senate Majority Leader McConnell "condemned the decrease in journalistic standards" following the Times story. During a briefing with reporters, McConnell said, "I'm distressed about the declining journalistic principles so much on display across all of the world of journalism, up to and

including of all publications, the New York Times. ... It's a very distressing development." McConnell said the Times "ought to be embarrassed."

Pressley Introduces Impeachment Resolution Against Kavanaugh. USA Today (9/17, Wu, 10.31M) reports that in the wake of the Times report, Rep. Ayanna Pressley (D-MA) has introduced an impeachment resolution against Kavanaugh. In a statement to Boston public radio station WBUR, Pressley said, "I believe Christine Blasey Ford. I believe Deborah Ramirez. It is our responsibility to collectively affirm the dignity and humanity of survivors. ... Sexual predators do not deserve a seat on the nation's highest court, and Brett Kavanaugh's confirmation process set a dangerous precedent. ... We must demand justice for survivors and hold Kavanaugh accountable for his actions." USA Today adds that Pressley's resolution "is unlikely to go anywhere" because "Democratic leadership seems to have little appetite for a fight over impeachment."

Harris Calls On House Judiciary Committee To Investigate Kavanaugh. Reuters (9/17, Becker) reports Sen. Kamala Harris (D-CA) on Tuesday urged the House Judiciary Committee to investigate Kavanaugh in light of the new allegations. In a letter to Chairman Jerrold Nadler, Harris, who has called for Kavanaugh's impeachment, said the panel "hold Mr. Kavanaugh accountable for his prior conduct and testimony."

Gorsuch Says He Opposes "Nine Older People Sitting In Washington Making Stuff Up." The Washington Examiner (9/17, Quinn, 448K) reports that Supreme Court Justice Neil Gorsuch "is firing back at the critics of his judicial philosophy," including some of his brethren on the High Court, "who believe the Constitution should be interpreted differently in the modern era." Gorsuch "has positioned himself as a bulwark against" what he describes as "nine older people sitting in Washington making stuff up." Said Gorsuch, "When that happens, your rights get diminished and the Constitution gets amended in ways you never agreed to." The Examiner adds that while Gorsuch did not mention President Trump, "he did make an impassioned plea for 'civility' that could be seen by some as a veiled shot at Trump, who even his supporters would concede adopts a brutish coarseness, often via Twitter, to communicate."

New York Judge Steps Down After Posting Trump Slogan With An Image Of A Noose. The New York Times (9/17, Otterman, 18.61M) reports that six weeks after Kyle Canning he became a judge in Altona, New York in January 2018, "he posted an image of a noose in front of a black background on his Facebook page." The post, which read, "IF WE WANT TO MAKE AMERICA GREAT AGAIN WE WILL HAVE TO MAKE EVIL PEOPLE FEAR

PUNISHMENT AGAIN," was "brought to the attention of the state Commission on Judicial Conduct." After an investigation was opened, Canning "stepped down." While Canning's post included President Trump's campaign slogan, Canning, who is not a lawyer, "said he did not read it that way when he publicly shared it to his Facebook page." He "said he thought the post was supporting the death penalty, and he did not consider its racial connotations." Said Canning, "There is not a man that I could despise more than Donald Trump."

Sinema Faces Arizona "Censure" For Voting To Confirm Trump Nominees. The Washington Examiner (9/17, Brown, 448K) reports that Sen. Kyrsten Sinema (D-AZ) "is facing possible censure from the liberal caucus" of the Arizona Democratic Party for "failing to support the tenets of the 2016 Democratic Party Platform." A censure resolution from the caucus which will be considered at the party's quarterly meeting on Saturday, "delineate[s] the reasons why Sinema has, in the estimation of the caucus, failed to live up to those tenets when she voted to confirm" Attorney General Barr and Interior Secretary Bernhardt, "as well as neglecting to co-sponsor legislation that would reinstate net neutrality rules."

Cook To Leave Congress, Plans To Run For County Supervisor. The Palm Springs (CA) Desert Sun (9/17, Metz, 131K) reports Rep. Paul Cook (R-CA) "announced his intention to retire...after completing his fourth term in January 2021 in order to run for San Bernardino County District 1 Supervisor." Cook "was first elected in 2012 after serving six years in the California State Assembly," and "joins 11 other Republican members of Congress who've announced they won't be seeking reelection." Cook is, says the Los Angeles Times (9/17, Mai-Duc, 4.64M), "the first to announce his retirement in California's Republican US House delegation, which has been greatly diminished in recent years," as "in the 2018 midterms, Democrats took control of half of the 14 remaining Republican seats in California, which has a total of 53 congressional districts."

The Hill (9/17, Rodrigo, Brufke, 2.98M) reports "President Trump won Cook's district by more than 15 points in 2016," and "Cook won his last election there against another Republican with 60 percent of the vote." Politico (9/17, Zanona, White, 4.29M) indicates Cook "was backed by Trump in his race last year against former Assemblyman Tim Donnelly, a Tea Party favorite" and co-founder of an anti-immigration group "that monitors the border." The CNN (9/17, Byrd, 83.16M) website calls CA8 "safely Republican."

The AP (9/17, Beam) reports that in a statement, "Cook hinted at frustrations with the bureaucracy in Washington." The San Bernardino (CA) Sun (9/17, Emerson, 129K) quotes him as saying, "After twenty-six years in the Marine Corps,

my attention turned first to local government,” and “while I’ve been called to serve in other capacities such as Congress, my focus has always been on empowering communities and making sure local residents have the strongest voice in decisions that affect them.”

DOJ Lawsuit Seeks All Proceeds From Snowden’s Memoir. The AP (9/17, Balsamo) reports that Justice Department has filed a lawsuit against former National Security Agency contractor Edward Snowden, “alleging he violated nondisclosure agreements by publishing a memoir without giving the government an opportunity to review it first.” DOJ is “seeking to ‘recover all proceeds’ from Snowden’s book, which was released Tuesday.”

The New York Times (9/17, Savage, 18.61M) reports in the lawsuit, the DOJ “complained that by publishing the book, Mr. Snowden violated his legal obligation to let censors at the C.I.A. and the N.S.A. vet the manuscript first, and so he had to forfeit any profits.” However, Ben Wizner, an American Civil Liberties Union lawyer who represents Snowden, “said that the book contained no classified information that the news media had not previously published.”

The Washington Post (9/17, 14.2M), Reuters (9/17), and Bloomberg (9/17, Larson, 4.73M) also cover the lawsuit.

Conservative Groups Urge Administration To Weaken Standards For Home Appliances. The New York Times (9/17, Tabuchi, 18.61M) reports on “a broad campaign coordinated by conservative organizations with ties to fossil-fuel companies,” aimed at persuading the Trump Administration “to weaken standards on a long list of home appliances.” The Times story focuses on what it describes as “the dishwasher lobby.” It cites an online petition from FreedomWorks that reads, “Dishwashers used to clean a full load of filthy dishes in under an hour. But now they take an average of two and a half hours and STILL leave dishes dirty!” This site attributes this decline to “crazy environmentalist rules.” The Times also reports that the dishwasher effort is “one of many cases where a Trump administration regulatory rollback is in fact opposed by the very industry the White House claims it will help.” Jennifer Cleary of the Association of Home Appliance Manufacturers wrote in a 2018 letter to Administration officials that weakening the standards would mean “additional costs for manufacturers and, ultimately, consumers.”

Army Experiments With New Recruiting Tactics. The Wall Street Journal (9/17, Kesling, Subscription Publication, 7.57M) reports that the US Army last year recruited just under 70,000 troops, which was about 10 percent less than its goal. Now, in a pilot program in Chicago, the Army is trying new recruiting tactics which use

market data to adjust its message by neighborhood and conform its advertising and staffing to the demographics of the area.

Car Crashes Into Lobby Of Trump Tower In New Rochelle. The New York Post (9/17, Musumeci, 4.57M) reports, “A car plowed into the lobby of Trump Plaza in New Rochelle Tuesday night.” video posted on social media “shows a banged-up black Mercedes-Benz sitting inside the marble lobby of the 40-story luxury residential building.” CBS New York reporter Tony Aiello tweeted, “Workers at Trump Plaza New Rochelle say after car plowed into lobby, make [sic] driver got out and took a seat on a sofa. Said nothing. Several injuries but none are life threatening.” The New York Times (9/17, Zaveri, Padilla, 18.61M) says that while police were still investigating, the crash “did not appear to be intentional, said Sgt. Chris Castiglia of the New Rochelle Police Department.” The Washington Times (9/17, Morton, 492K) also reports on the crash.

Veteran Journalist Cokie Roberts Dies. All three network news broadcasts reported on the death of journalist Cokie Roberts, who died Tuesday of complications from breast cancer. The CBS Evening News (9/17, story 12, 1:41, O'Donnell, 4.34M) reported Roberts, whose parents were both members of Congress from Louisiana, was “a best selling author, correspondent, political analyst, and anchor.” On NBC Nightly News (9/17, story 9, 1:43, 5.96M), Lester Holt called Roberts “one of the best in our business.” David Muir said on ABC World News Tonight (9/17, story 7, 4:18, 6.62M) that Roberts “had a brilliant mind, matched only by her kindness, her grace and, of course, her wit.”

USA Today (9/17, Behrmann, 10.31M) reports that President Trump commented on Roberts’ passing by calling her a “professional,” but adding that she “never treated me nicely.” Speaking to reporters aboard Air Force One, Trump said, “I never met her. She never treated me nicely. But I would like to wish her family well. She was a professional, and I respect professionals. I respect you guys a lot, you people a lot. She was a real professional. Never treated me well, but I certainly respect her as a professional.”

RNC Raised “Record-Setting” \$23.5M In August. In an exclusive, Fox News (9/17, Re, 27.59M) reports in an online article that the RNC “is expected to announce this week that it raised a record-setting \$23.5 million in August and had \$53.8 million cash on hand as of the end of that month – signaling growing GOP momentum heading into the 2020 elections.” The group’s “August fundraising total was the highest recorded in August during an off-cycle year by either the RNC or DNC, and the RNC has not had as much cash on hand since September 2016, just before Election Day. The RNC’s figures included only

money directly contributed to the committee and did not include money contributed to any other joint committee."

Trump Camp Severs Ties With Key Florida Adviser At DeSantis' Urging. Politico (9/17, Isenstadt, Dixon, 4.29M) reports that President Trump's campaign "has severed ties with Florida adviser Susie Wiles, leaving the president without a top adviser in a major battleground state going into the 2020 election. The move was made at the urging of Florida Gov. Ron DeSantis, who has been attempting to install his own allies in the state party." Politico says Wiles' exit "followed weeks of behind-the-scenes drama that has prompted turnover at the highest levels of the state GOP apparatus. DeSantis personally made it clear he wanted Wiles out, according to two senior Republicans familiar with discussions between DeSantis and the Trump campaign."

Businessman In North Macedonia "Hijacked" Facebook Page "Vets For Trump." The Washington Post (9/17, Timberg, 14.2M) reports, "The Facebook page 'Vets for Trump' was for most of its existence exactly what it seemed: a place where former US service members touted Donald Trump, discussed veterans issues and shared conservative memes with its more than 100,000 followers. Then in March, say its longtime operators, a North Macedonian businessman hijacked it, leaving the Americans to watch helplessly as their page began operating under foreign control. Their messages seeking help from Facebook led to months of miscommunication and inaction." The incident, says the Post, "underscores how money, politics and online misinformation remain deeply and often invisibly entangled ahead of the 2020 presidential election, despite years of promises by government officials and technology companies to combat such problems."

WSJournal: GOP Leaders Shouldn't Cancel Presidential Primaries. In an editorial, the Wall Street Journal (9/17, Subscription Publication, 7.57M) urges Republican Party leaders not to cancel presidential primaries in their states. The Journal argues that the three Republicans currently seeking to challenge President Trump, while long-shots, are serious candidates that could make compelling policy proposals that deserve to be heard.

NBC/WSJournal Poll: Biden 31%; Warren 25%; Sanders 14%; Buttigieg 7%; Harris 5%. On its website, NBC News (9/17, Murray, 6.14M) reports that a national NBC News/Wall Street Journal poll of 506 Democratic primary voters, taken Sept. 13-16, shows ex-Vice President Joe Biden leading the race for the 2020 Democratic presidential nomination with 31%, followed by Sen. Elizabeth

Warren (D-MA) at 25%, Sen. Bernie Sanders (I-VT) at 14%, South Bend Mayor Pete Buttigieg at 7%, and Sen. Kamala Harris (D-CA) at 5%; no other contender topped 4%. In a similar poll taken in July, Biden led with 26%, followed by Warren at 19%, and Harris and Sanders each at 13%. The Wall Street Journal (9/17, Thomas, Subscription Publication, 7.57M) reports that the poll was conducted in the wake of last week's Democratic presidential debate.

On its website, CNBC (9/17, Harwood, 3.62M) reports that Biden "commands 49% among African-Americans, 46% among senior citizens, and 42% among moderate and conservative Democrats." Warren, meanwhile, "leads Biden by roughly two-to-one among liberals and Democrats under 35, breaks even among whites, and holds a double-digit edge among those seeking large-scale change in the post-Trump era." In addition, "Warren now holds a clear edge in enthusiasm. Fully 70% of those polled 'describe themselves as enthusiastic or comfortable about her candidacy, more than for either Biden or Sanders. As a result, 45% of Democratic primary voters call Warren either their first or second choice. That compares to 41% for Biden, 29% for Sanders, 19% for...Buttigieg and 14% for...Harris."

California Poll: Biden 26%; Sanders 26%; Warren 20%; Yang 7%; Harris 6%; O'Rourke 5%. An Emerson College poll of 424 California Democratic voters, taken Sept. 13-16, shows Biden and Sanders tied for the lead with 26% each, followed by Warren at 20%, entrepreneur Andrew Yang at 7%, Harris at 6%, and ex-Rep. Beto O'Rourke (D-TX) at 5%; no other contender tops 4%. The Hill (9/17, Greenwood, 2.98M) reports, "The survey is a sign that Harris may face a difficult battle in her home state's nominating contest, a delegate-rich election that carries more significance than ever because of an accelerated primary schedule that places it on Super Tuesday, when voters in a dozen states will cast their ballots for the Democratic nomination. 'Senator Kamala Harris is in trouble in her home state. If she is unable to gain momentum in Iowa or New Hampshire, come Super Tuesday she might have a similar fate to Sen. Marco Rubio in 2016, when he was unable to win his home state of Florida and dropped out of the race,' Emerson Polling Director Spencer Kimball said."

New York Poll: Biden 22%; Warren 17%; Sanders 15%. The New York Post (9/17, Campanile, 4.57M) reports that a Siena College poll of 359 New York Democratic voters, taken Sept. 8-12, shows Biden leading with 22%, followed by Warren at 17%, and Sanders at 15%; no other candidate topped 4%. In a separate article, the New York Post (9/17, Campanile, 4.57M) reports that New York City Mayor Bill de Blasio "is registered as having '0' support from Big Apple Democrats in" in the survey.

Trump Camp Out With Video Targeting Biden

On Gaffes. USA Today (9/17, Santucci, 10.31M) reports that President Trump's campaign takes aim at former Vice President Joe Biden's "frequent slip-ups in a new video released Tuesday." Trump campaign manager Brad Parscale "tweeted the video, which strings together clips of Biden's verbal gaffes and political commentators questioning his ability to lead the nation. The video shows Biden mixing up his words, confusing which state he was speaking in and on more than one occasion accidentally referring to fellow primary candidates as 'the president.'"

In an online article, Fox News (9/17, Steinhauer, 27.59M) reports that the video "stitches together everything from [Biden's] recent debate-stage musing about 'record players' to his statement that 'poor kids' are just as talented as 'white kids.' Interspersed with the clips of the 76-year-old Biden's comments are those of pundits wondering about his stumbles, shakiness, mental and physical stamina, whether he's 'lost a step' and whether he's 'equipped for a very grueling campaign.'" The Hill (9/17, Coleman, 2.98M) reports that the video includes a clip of Sen. Cory Booker (D-NJ) "saying in an interview, 'There are definitely moments where you listen to Joe Biden and you just wonder.' The video ends with Biden sitting amongst an audience, with his eyes closed and seemingly asleep."

Reuters Analysis: Biden's Leftward Shift On Environment May Hurt Him In Rust Belt. Under the headline "Biden's Bid To Attract Rust Belt Workers Faces Troubles In His Own Backyard," Reuters (9/17, Renshaw) reports that over "a dozen current and former union leaders and workers who spoke to Reuters recently in Philadelphia, questioned" Biden's "loyalty." Reuters reports that the union leaders say that "in embracing calls to phase out the fossil fuel industry that many of the region's pipefitters and steelworkers rely on for jobs," Biden "risks losing his 'hard-hat' appeal in a critical swing state. 'I think Biden has taken our votes for granted. Our plant closed and we didn't hear from him,' said Ryan O'Callaghan, the former union head of a now-shuttered Philadelphia refinery." Reuters says Biden's "silence on the refinery...suggests how the party's aggressive environmental agenda may be boxing Biden out of an issue that seemingly plays into his brand of politics."

WSJournal Analysis: Biden Walking Tightrope On Economic Policy. Under the headline "'Nobody Has To Be Punished': Joe Biden's Economic Tap Dance," the Wall Street Journal (9/17, Schlesinger, Thomas, Subscription Publication, 7.57M) reports that on economic policy, Biden is walking a tightrope, offering plans that he hopes will appeal to the activist left but also won't turn off moderates. The Journal says that as Sens. Bernie Sanders (I-VT) and Elizabeth Warren (D-MA) push far-left plans on taxes and business

regulation, Biden is setting more moderate goals with his proposals on the same topics.

Trump Downplays Size Of Warren's NYC Crowd.

CQ Roll Call (9/17, Bennett, 154K) reports that President Trump, "who often touts the size of crowds at his events and knocks those of his foes, on Tuesday dismissed an audience" Sen. Elizabeth Warren (D-MA) "drew the night before in New York City. Warren spoke in front of the iconic arch in the Big Apple's Washington Square Park before an audience numbering in the 'thousands,' according to estimates from local media outlets." However, Trump, speaking with reporters in California, said, "Anybody that can't get people standing in the middle of Manhattan in the most densely populated area of the country – anybody could do that. I think more Democrats should do it. I get these crowds in areas that nobody's ever seen crowds before. Pretty amazing."

The Hill (9/17, Easley, Samuels, 2.98M) reports that the Warren camp "estimated that 20,000 people filled Washington Square Park on Monday night to hear the candidate give a speech about how she would root out corruption in Washington if she's elected president." However, Trump "questioned whether Warren actually got as big of a crowd as her campaign claimed. 'Number one, she didn't have 20,000 people and number two, I think anybody would get a good crowd there,' he said. 'I think you have a good crowd there if you don't even go there, just say you're going and how many people are in the park.'"

The Washington Post (9/17, Parker, Linskey, 14.2M) reports, "Once widely regarded as an interesting but ultimately inconsequential novelty of political campaigns, crowd size is now a potentially meaningful metric of electability – one that can translate into volunteers, donors and, as Trump demonstrated in 2016, actual momentum. ... The multitudes who gathered after a light rain to hear Warren's plan to fix what she describes as systematic corruption – and to cheer her rebuke of Trump as 'corruption in the flesh' – provided clear evidence that Warren, even in a Democratic primary, can compete on the same terms as a president who revels in crowd size above almost all else."

Warren Draws Large New York Crowd To Hear Her Tie Trump To Washington Corruption. The AP (9/17, Weissert) reports that the "thousands of people packed under the marble arch of Manhattan's Washington Square Park to hear...Warren on Monday" were "the product of a carefully planned, data-driven strategy to identify supporters, attract them to a rally and ultimately convert them into voters, a plan that goes well beyond producing a compelling scene for television." According to the AP, "In an era where campaigns increasingly try to leverage technology to tactical advantage, the attention to detail by Warren's team stands out." The AP

says Warren has “mastered the art of drawing thousands to her rallies, but, more importantly, those turning out are also a proxy for her recent rise in the polls.”

The New York Times (9/17, Burns, 18.61M) reports that in her speech, Warren “proposed a battery of new reforms in her remarks in New York City’s Washington Square Park, near the 1911 Triangle Shirtwaist factory fire that she cited as an example of the oppression of the working class. And she highlighted an array of other reforms she has previously outlined, including a ban on lobbying by foreign governments and new ethics regulations on presidents and judges.” According to the Times, Warren “presented herself not just as an opponent of” Trump, “whom she called ‘corruption in the flesh,’ but of the Washington system writ large.”

Politico Analysis: Top Sanders Allies Worry He’s Being Eclipsed By Warren.

Politico (9/17, Otterbein, Spiner, 4.29M) reports that some of the “fiercest supporters” of Sen. Bernie Sanders (I-VT) “are sounding the alarm that the campaign is bogged down by disorganization, personality clashes, and poor communication between state operations and national headquarters.” Following two “setbacks this week – the acrimonious shakeup of his staff in New Hampshire on Sunday and loss of the Working Families Party’s endorsement to Elizabeth Warren a day later – Sanders’ allies and former aides are worried that recent disappointments are not one-off stumbles but rather emblematic of larger problems.” However, Sanders adviser Jeff Weaver claims that “numerous rank-and-file members in the Working Families Party support Sanders and that his ground game in New Hampshire and other early states is strong.”

Carter Says He Doesn’t Think He Could Handle Duties Of Presidency At 80.

The AP (9/17, Barrow) reports that former President Jimmy Carter, 94, “said Tuesday he doesn’t believe he could have managed the most powerful office in the world at 80 years old.” He “didn’t tie his comments to any of his fellow Democrats running for president, but two leading 2020 candidates, Joe Biden and Bernie Sanders, would turn 80 during their terms if elected. Biden is 76. Sanders is 78. ‘I hope there’s an age limit,’ Carter said with a laugh as he answered audience questions at his annual report at the Carter Center in Atlanta. ‘If I were just 80 years old, if I was 15 years younger, I don’t believe I could undertake the duties I experienced when I was president.’”

Ocasio-Cortez Endorses Liberal Newman’s Primary Challenge To Lipinski.

Politico (9/17, Forgey, 4.29M) reports that Rep. Alexandria Ocasio-Cortez (D-NY) on Tuesday backed “liberal” Marie Newman in her 2020 primary challenged to Rep. Dan Lipinski (D-IL) – the

New York lawmaker’s “first endorsement of a candidate aligned with the progressive group Justice Democrats since being elected to Congress.” Politico says “the left-wing political action committee, which aims to challenge more moderate Democratic incumbents, announced” Ocasio-Cortez’s endorsement in a tweet. The Chicago Tribune (9/17, Pearson, 2.65M) quotes Ocasio-Cortez as saying, “Marie Newman is a textbook example of one of the ways that we could be better as a party – to come from a deep blue seat and to be championing all the issues we need to be championing. The fact that a deep blue seat is advocating for many parts of the Republican agenda is extremely problematic. We’re not talking about a swing state that is being forced to take tough votes.”

Writing for the Chicago Sun-Times (9/17, 875K), Lynn Sweet says that the endorsement “by the controversial, charismatic” Ocasio-Cortez “could turn out progressives and turn off centrists in the suburban Chicago district. Lipinski’s team seemed little concerned by the popular but polarizing Ocasio-Cortez embracing Newman. I wouldn’t be surprised if Lipinski talks about Ocasio-Cortez more than Newman in the run up to the March Illinois primary. Lipinski, who will need crossover GOP voters to win the nomination in the safe Democratic district, is counting on a backlash to Ocasio-Cortez and, by extension, her provocative allies.”

The New York Times (9/17, Edmondson, 18.61M) reports that Newman unsuccessfully challenge Lipinski last year, losing “by about 2,000 votes.” The Times says Lipinski “bills himself in his campaign ads as ‘a workhorse, not a show horse,’ and the eight-term congressman, who opposes abortion rights and voted against the Affordable Care Act, has repeatedly expressed his concerns that it is ‘detrimental’ for the party to push out conservative lawmakers.” The Washington Post (9/17, Itkowitz, 14.2M) says Lipinski is “one of the last remaining conservative Democrats in Congress who oppose abortion rights,” which “has alienated him from most of the party and prompted other, more centrist Democrats...to support his challenger.” HuffPost (9/17, Miller, 1.67M) also reports on the story.

NYTimes Analysis: Some “Experts” Say Redrawn NC Political Maps Still Favor Republicans.

The New York Times (9/17, Wines, 18.61M) reports, “When a North Carolina state court struck down the state’s legislative political maps nearly two weeks ago, it said the maps had been drawn ‘with surgical precision’ to keep Republicans in control of both chambers.” Yesterday, lawmakers “approved new electoral maps – drawn under a court directive to ignore partisan considerations – that appear to give Republicans a slight political edge, some experts said.” The Times adds, “The state court that threw out the original maps will have the final say this fall and will rule on

their fairness after an analysis by a Stanford University expert."

WSJournal: Murkowski's Move To Protect Alaska's Salmon Industry Hurts Consumers.

In an editorial, the Wall Street Journal (9/17, Subscription Publication, 7.57M) takes issue with Republicans who claim to support free markets, except when competition threatens interests in their home state, specifically calling out Sen. Lisa Murkowski (R-AK) for her efforts to protect Alaska's Pacific salmon industry. The editorial criticizes Murkowski for a rider she is expected to insert in a bill this week to block the sale of genetically modified salmon. The move will hurt consumers, the Journal says, and urges Murkowski's colleagues to strip the rider from the bill.

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From: Ferguson, Steve (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AEC79B088CE947819EADD4BF420AA54B-FERGUSOS]
Sent: 9/16/2019 3:27:15 PM
To: Thomas, Gina (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a7d21227e5643548f0a7c256b54f83f-gthomas]; Rogers, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b23ef4ca2fa14a6eb174ee611953a396-rogersk]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]
CC: Goldstein, Bruce (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]
Subject: RE: Request for Input - 52478 Cassedy

Sorry but the message itself from the FOIA office is confusing.

The actual FOIA request from KEI is regarding an exclusive FR notice for Theragen but the message from the FOIA office is asking about an exclusive FR notice for Genetic Therapy, Inc. Both notices are in the same FR issue with me as the Technology Licensing Specialist.

Regarding the FR notice for Theragen,

b4,b5

b4,b5

Steve

Steven M. Ferguson, CLP
Special Advisor
NIH Office of Technology Transfer
6011 Executive Boulevard, Suite 325
Rockville, MD 20852
Phone: (301) 435-5561
Fax: (301) 402-0220
Email: sf8h@nih.gov
Web: www.ott.nih.gov

From: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>
Sent: Monday, September 16, 2019 10:06 AM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Cc: Goldstein, Bruce (NIH/OD) [E] <goldsteb@mail.nih.gov>; Ferguson, Steve (NIH/OD) [E] <fergusos@od6100m1.od.nih.gov>
Subject: RE: Request for Input - 52478 Cassedy

REL0000024921

Karen,

Unless Steve still has these documents in his archive, we may not have anything responsive. This is for documents that are 27 years old. I was wondering if we would even have information that far back. Plus I think under normal circumstances most of these register notice comments are usually discarded after 10 or 15 years.

Gina

From: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>
Sent: Monday, September 16, 2019 9:59 AM
To: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Cc: Goldstein, Bruce (NIH/OD) [E] <goldsteb@mail.nih.gov>; Ferguson, Steve (NIH/OD) [E] <fergusos@od6100m1.od.nih.gov>
Subject: RE: Request for Input - 52478 Cassedy

Hi Gina – Forwarding this to Mark and Dale for guidance. They are providing guidance on other similar requests. Thanks, Karen

Karen Rogers
Acting Director
Senior Royalties Administrator
Office of Technology Transfer
6011 Executive Blvd, Suite 325
Rockville, MD 20852
Phone: 301-435-4359

From: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>
Sent: Monday, September 16, 2019 9:54 AM
To: Ferguson, Steve (NIH/OD) [E] <fergusos@od6100m1.od.nih.gov>
Cc: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>; Goldstein, Bruce (NIH/OD) [E] <goldsteb@mail.nih.gov>
Subject: FW: Request for Input - 52478 Cassedy

Good morning Steve,

The following FOIA request is in regards to a Federal Register notice that dates back to 1992.

Do you think you would still have any documents relative to this request?

Gna

From: NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>
Sent: Friday, September 13, 2019 4:54 PM
To: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>
Cc: NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>
Subject: Request for Input - 52478 Cassedy

Good Afternoon Gina,

Please see the attached request (and related document) for input regarding copies of all comments, objections, and license applications filed in response to the following Federal Register (FR) notice: "National Institutes of Health: Prospective Grant of Exclusive License; Adeno-Associated Virus (AAV) Vectors for Gene Therapy" (1992) <https://cdn.loc.gov/service/ll/fedreg/fr057/fr057169/fr057169.pdf>

Please let us know if this should go to a different IC or office.

Thanks.

Roger Bordine

Program Support
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633

Fax: 301-402-4541

Roger.bordine@nih.gov



National Institutes of Health
Turning Discovery Into Health

From: Berkson, Laura (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ADB561AB47E54FDC94E2A54682514434-BERKSONLD]
Sent: 3/18/2020 12:00:46 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Puglielli, Maryann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f53ceacaf754875a948081bac5cc66a-pugliellim]
Subject: RE: Request from Senator Sanders' office

Hi Mark,

If I recall correctly, we had a call with Senator Sanders office on this topic in early 2019, basically repeating the info in the background document we sent her. I haven't heard from Senator Sanders's office on this topic for over a year now and I am not aware of any outstanding requests from the office.

Hope that helps!

Laura

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Tuesday, March 17, 2020 7:14 PM
To: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Cc: Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>
Subject: RE: Request from Senator Sanders' office

Laura:

Where are we with this?

Thanks,
Mark

From: Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>
Sent: Thursday, March 12, 2020 3:05 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: FW: Request from Senator Sanders' office

Hi Mark --

Just following up on this. Were you and Laura able to resolve this matter with Senator Sanders's office?

Thanks,
Maryann

Maryann T. Puglielli, Ph.D., J.D.
Lead Technology Transfer and Patent Specialist



Technology Transfer and Intellectual Property Office
Branch A
5601 Fishers Lane, Suite 6D, MSC 9804

Rockville, MD 20892-9804
(240) 627-3723

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From: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Sent: Thursday, February 14, 2019 4:17 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>
Cc: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Subject: RE: Request from Senator Sanders' office

Thanks, Mark. I fully agree that a conversation is the most sensible way to bring this to closure.

Can you also please ask that Peter be removed from future email exchanges?

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, February 14, 2019 4:12 PM
To: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>
Cc: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>
Subject: Re: Request from Senator Sanders' office

It is difficult to explain all of this. I think the best response would be for Laura and me to talk to them about these issues.

Sent from my iPhone

On Feb 14, 2019, at 3:43 PM, Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov> wrote:

Dear Dale, Mark, Mike, Maryann, Rick and Suzanne,

FYI, here is OLPA's initial response.

Peter Soukas
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Phone: 301-594-8730
Email: ps193c@nih.gov

From: Berkson, Laura (NIH/OD) [E]
Sent: Thursday, February 14, 2019 3:42 PM
To: [REDACTED] (Budget) [REDACTED] <budget.senate.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi [REDACTED]

I'm going to share these with a few of my colleagues and will be back in touch soon.

REL0000024962

Best,
Laura

From: [b6] (Budget) [b6] <[b6]@budget.senate.gov>
Sent: Thursday, February 14, 2019 3:27 PM
To: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, thank you for this reply. I have a couple initial questions after reading this through.

- Your reply says that NIH will take steps to ensure that the proposed terms and scope of exclusivity are not greater than reasonably necessary. What are those steps? In what ways might or will NIH limit the proposed terms and scope of exclusivity? If you haven't taken those steps in this case yet and so cannot specify, please provide examples of steps NIH may take or has taken that might be applicable in this situation.
- Related – has NIH issued an exclusive license (let's say in the last 20 years) for a duration less than the full term of the patent? If so, which licenses, and what factors led to the decision to choose a term less than the life of the patent in that exclusive license?
- Your response mentions that your experienced licensing professionals obtain the best terms possible when negotiating these agreements, which are designed to improve the chances of successful development of the licensed therapy or vaccine and its distribution to patients throughout the world. Could you provide me with examples of these "best terms possible," including any provisions in existing exclusive licenses that address the policy objective set out in the US PHS Technology Transfer Policy Manual: "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."
- One of the things we requested was a copy of the patent application. I understand that this patent application is still provisional and has not yet been published. Does NIH license patent applications before they are available to the public? If so, why? Why does NIH open (and close) a public comment period before that information is available to the public?

Thanks, [b6]

From: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Sent: Thursday, February 7, 2019 4:47 PM
To: [b6] (Budget) [b6] <[b6]@budget.senate.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi [b6]

We really appreciate your patience as we pulled together this information. I'm happy to report that the response to KEI's letter to NIH was sent this week. I am attaching a document that includes some background about NIH and exclusive licenses and some information about the specific potential license in question. I hope you find it helpful.

Best,
Laura

From: [b6] Budget) [b6] budget.senate.gov>
Sent: Thursday, February 7, 2019 4:17 PM
To: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, we are still waiting to receive these documents. It's been a month - when will we receive the information requested?

Thanks,

[b6]

From: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Sent: Thursday, January 31, 2019 2:14 PM
To: [b6] Budget) [b6] budget.senate.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi [b6]

My apologies for the confusion. We are still prepared preparing the background information and formal response. We expect to have both complete and ready to send to you early next week.

Laura

From: [b6] Budget) [b6] budget.senate.gov>
Sent: Thursday, January 31, 2019 10:39 AM
To: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura,

Good morning. When we spoke a week ago my understanding was that you would be sending over some background documents that you had on hand immediately following the call and would also get back to me "soon" with the documents we requested. When can we expect to receive that?

Thanks,

[b6]

From: [b6] Budget)
Sent: Thursday, January 24, 2019 12:43 PM
To: 'Berkson, Laura (NIH/OD) [E]' <laura.berkson@nih.gov>
Cc: 'Soukas, Peter (NIH/NIAID) [E]' <peter.soukas@nih.gov>; 'Pollock, Rachel (NIH/OD) [E]' <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, thanks for calling yesterday. Could you send over those background/process documents you mentioned? We'll stand by for the substantive response. Happy to talk again about next steps once we see what you're able to provide.

Thanks,

b6

From: b6 (Budget)
Sent: Wednesday, January 23, 2019 3:28 PM
To: 'Berkson, Laura (NIH/OD) [E]' <laura.berkson@nih.gov>
Cc: 'Soukas, Peter (NIH/NIAID) [E]' <peter.soukas@nih.gov>; 'Pollock, Rachel (NIH/OD) [E]' <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, I just left you a voicemail. Could you please give me a call as soon as possible? My direct is b6

b6

Thanks,

b6

From: b6 (Budget)
Sent: Wednesday, January 16, 2019 5:13 PM
To: 'Berkson, Laura (NIH/OD) [E]' <laura.berkson@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, any updates? I understand if this information may take a little time to assemble – in the meantime it would be terrific if it's possible to get the comment period extended. Thanks, b6

From: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Sent: Thursday, January 10, 2019 4:23 PM
To: b6 (Budget) b6 @budget.senate.gov
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi b6

We've reached out to our subject matter experts on this and will be back in touch soon.

Best,
Laura

Laura Berkson, J.D.
Office of Legislative Policy & Analysis
National Institutes of Health
(301) 496-3471 | laura.berkson@nih.gov

From: b6 (Budget) b6 @budget.senate.gov
Sent: Thursday, January 10, 2019 2:58 PM
To: Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Berkson, Laura (NIH/OD) [E]

<laura.berkson@nih.gov>

Subject: RE: Request from Senator Sanders' office

Thanks Adrienne. Laura, I look forward to hearing from you soon. Thanks,

b6

From: Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>

Sent: Wednesday, January 9, 2019 7:04 PM

To: b6 (Budget) b6 budget.senate.gov

Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>

Subject: Re: Request from Senator Sanders' office

Hi b6

Thanks for your note. I'm CC'ing Laura Berkson who will coordinate with NIAID to get you the information you need.

Hope you're enjoying the new Congress!
Adrienne

On Jan 9, 2019, at 5:04 PM, b6 (Budget) b6 budget.senate.gov wrote:

Dear Mr. Soukas and Adrienne,

I hope you are both doing well. Would it be possible to extend the comment period for 83 FR 65696 [HHS Reference No. E-018-2018-0] regarding the provisional patent application entitled "Chimeric Vaccines?" My understanding from reading the FR notice is that the comment period began on December 21 and ran through just January 7. We'd appreciate additional time to review information regarding this important potential license that may have domestic and global public health implications.

To that end, could you send me a copy of the patent application and a list of the countries where NIH will file patents? I am attaching the letter from Knowledge Ecology International and Doctors Without Borders that was sent to your office; I respectfully request that in addition to providing this information to me, you also provide KEI and MSF with the information they are requesting in a timely way before making any decisions about the potential exclusive license.

Thank you, b6

b6

Senior Advisor on Poverty and Health
Senate Budget Committee
Ranking Member Bernie Sanders

b6

budget.senate.gov

<Medigen Vaccines Biologics Corp. (Medigen), having a place of business i....pdf>

REL0000024962

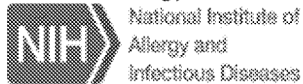
From: Puglielli, Maryann (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9F53CEACAF754875A948081BAC5CC66A-PUGLIELLIM]
Sent: 3/17/2020 9:43:43 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Williams, Richard (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5f89fe4d27a43abb936bb20efeca3b9-rwilliams]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]
Subject: FW: Request from Senator Sanders' office

Hi Mark —

If I can get an update on this in the next day or two, I'd appreciate it.

Thanks,
Maryann

Maryann T. Puglielli, Ph.D., J.D.
Lead Technology Transfer and Patent Specialist



Technology Transfer and Intellectual Property Office
Branch A
5601 Fishers Lane, Suite 6D, MSC 9804
Rockville, MD 20892-9804
(240) 627-3723

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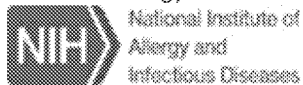
From: Puglielli, Maryann (NIH/NIAID) [E]
Sent: Thursday, March 12, 2020 3:05 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: FW: Request from Senator Sanders' office

Hi Mark —

Just following up on this. Were you and Laura able to resolve this matter with Senator Sanders's office?

Thanks,
Maryann

Maryann T. Puglielli, Ph.D., J.D.
Lead Technology Transfer and Patent Specialist



Technology Transfer and Intellectual Property Office
Branch A
5601 Fishers Lane, Suite 6D, MSC 9804
Rockville, MD 20892-9804

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From: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>

Sent: Thursday, February 14, 2019 4:17 PM

To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>

Cc: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>;

Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E]

<suzanne.frisbie@nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>

Subject: RE: Request from Senator Sanders' office

Thanks, Mark. I fully agree that a conversation is the most sensible way to bring this to closure.

Can you also please ask that Peter be removed from future email exchanges?

From: Rohrbaugh, Mark (NIH/OD) [E]

Sent: Thursday, February 14, 2019 4:12 PM

To: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>

Cc: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>;

Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Williams, Richard (NIH/NIAID) [E]

<rwilliams@niaid.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>

Subject: Re: Request from Senator Sanders' office

It is difficult to explain all of this. I think the best response would be for Laura and me to talk to them about these issues.

Sent from my iPhone

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Dear Dale, Mark, Mike, Maryann, Rick and Suzanne,

FYI, here is OLPA's initial response.

Peter Soukas
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Phone: 301-594-8730
Email: ps193c@nih.gov

From: Berkson, Laura (NIH/OD) [E]

Sent: Thursday, February 14, 2019 3:42 PM

To: [REDACTED] b6 Budget) [REDACTED] b6 <budget.senate.gov>

Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E]

<rachel.pollock@nih.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>

Subject: RE: Request from Senator Sanders' office

H [REDACTED] b6

I'm going to share these with a few of my colleagues and will be back in touch soon.

Best,
Laura

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Subject: RE: Request from Senator Sanders' office

Hi Laura, thank you for this reply. I have a couple initial questions after reading this through.

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Thanks, [b6]

From: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Sent: Thursday, February 7, 2019 4:47 PM
To: [b6] (Budget) <[b6]@budget.senate.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi [b6]

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Best,
Laura

REL0000024966

From: [b6] (Budget) [b6] <[b6]@budget.senate.gov>
Sent: Thursday, February 7, 2019 4:17 PM
To: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, we are still waiting to receive these documents. It's been a month - when will we receive the information requested?

Thanks,
[b6]

From: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Sent: Thursday, January 31, 2019 2:14 PM
To: [b6] (Budget) [b6] <[b6]@budget.senate.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi [b6]

My apologies for the confusion. We are still prepared preparing the background information and formal response. We expect to have both complete and ready to send to you early next week.

Laura

From: [b6] (Budget) [b6] <[b6]@budget.senate.gov>
Sent: Thursday, January 31, 2019 10:39 AM
To: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura,

Good morning. When we spoke a week ago my understanding was that you would be sending over some background documents that you had on hand immediately following the call and would also get back to me "soon" with the documents we requested. When can we expect to receive that?

Thanks,
[b6]

From: [b6] (Budget)
Sent: Thursday, January 24, 2019 12:43 PM
To: 'Berkson, Laura (NIH/OD) [E]' <laura.berkson@nih.gov>
Cc: 'Soukas, Peter (NIH/NIAID) [E]' <peter.soukas@nih.gov>; 'Pollock, Rachel (NIH/OD) [E]' <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, thanks for calling yesterday. Could you send over those background/process documents you mentioned? We'll stand by for the substantive response. Happy to talk again about next steps once we see what you're able to provide.

Thanks,

b6

From: b6 (Budget)
Sent: Wednesday, January 23, 2019 3:28 PM
To: 'Berkson, Laura (NIH/OD) [E]' <laura.berkson@nih.gov>
Cc: 'Soukas, Peter (NIH/NIAID) [E]' <peter.soukas@nih.gov>; 'Pollock, Rachel (NIH/OD) [E]' <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, I just left you a voicemail. Could you please give me a call as soon as possible? My direct is

b6

Thanks,

b6

From: b6 (Budget)
Sent: Wednesday, January 16, 2019 5:13 PM
To: 'Berkson, Laura (NIH/OD) [E]' <laura.berkson@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi Laura, any updates? I understand if this information may take a little time to assemble – in the meantime it would be terrific if it's possible to get the comment period extended. Thanks,

b6

From: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Sent: Thursday, January 10, 2019 4:23 PM
To: b6 (Budget) b6 budget.senate.gov
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>
Subject: RE: Request from Senator Sanders' office

Hi b6

We've reached out to our subject matter experts on this and will be back in touch soon.

Best,
Laura

Laura Berkson, J.D.
Office of Legislative Policy & Analysis
National Institutes of Health
(301) 496-3471 | laura.berkson@nih.gov

From: b6 (Budget) b6 budget.senate.gov
Sent: Thursday, January 10, 2019 2:58 PM
To: Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Berkson, Laura (NIH/OD) [E]

<laura.berkson@nih.gov>

Subject: RE: Request from Senator Sanders' office

Thanks Adrienne. Laura, I look forward to hearing from you soon. Thanks

b6

From: Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>

Sent: Wednesday, January 9, 2019 7:04 PM

To: Kasimow, Sophie (Budget) <Sophie_Kasimow@budget.senate.gov>

Cc: Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>

Subject: Re: Request from Senator Sanders' office

Hi b6

Thanks for your note. I'm CC'ing Laura Berkson who will coordinate with NIAID to get you the information you need.

Hope you're enjoying the new Congress!
Adrienne

On Jan 9, 2019, at 5:04 PM b6 Budget) b6 <@budget.senate.gov> wrote:

Dear Mr. Soukas and Adrienne,

I hope you are both doing well. Would it be possible to extend the comment period for 83 FR 65696 [HHS Reference No. E-018-2018-0] regarding the provisional patent application entitled "Chimeric Vaccines?" My understanding from reading the FR notice is that the comment period began on December 21 and ran through just January 7. We'd appreciate additional time to review information regarding this important potential license that may have domestic and global public health implications.

To that end, could you send me a copy of the patent application and a list of the countries where NIH will file patents? I am attaching the letter from Knowledge Ecology International and Doctors Without Borders that was sent to your office; I respectfully request that in addition to providing this information to me, you also provide KEI and MSF with the information they are requesting in a timely way before making any decisions about the potential exclusive license.

Thank you, b6

b6

Senior Advisor on Poverty and Health
Senate Budget Committee
Ranking Member Bernie Sanders

b6

@budget.senate.gov

<Medigen Vaccines Biologics Corp. (Medigen), having a place of business i....pdf>

REL0000024966

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 9/12/2019 8:27:04 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Further responses to KEI

From: Burke, Andy (NIH/NCI) [E]
Sent: Thursday, September 12, 2019 4:26 PM
To: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Subject: RE: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Ms. Ardizzone,

Answers to your questions are provided below.

Regards,

Andy

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Thursday, September 12, 2019 1:38 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>
Subject: Re: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Thank you for your response, Dr. Burke.

I have an additional question about the licenses. The FR notice lists three NIH OTT Reference Numbers. As far as I understand, those numbers are assigned to an invention when one is disclosed by an NIH intramural researcher. Or, at the very least, each number pertains to its own invention. **Can you please confirm that three inventions would be covered by the license?** Answer: The number of patentably distinct inventions will be determined during prosecution at the relevant patent offices.

Also, I understand that it is part of NIH's licensing policy to publish licensing opportunity notices on its OTT website. When I searched the numbers listed on the search engine here: <https://www.ott.nih.gov/opportunities>, no results were returned. **Why is that?** Answer: Please see previous response in my email of September 10.

Thank you again for your time and attention to this matter.

Kathryn Ardizzone

On Wed, Sep 11, 2019 at 4:45 PM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Dear Ms. Ardizzone,

REL0000024997

Answers to your questions are provided below.

Regards,

Andy

From: kathryn ardizzone <kathrynardizzonekei@gmail.com>
Sent: Wednesday, September 11, 2019 2:29 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>
Subject: Re: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Dr. Burke:

Thank you for your response.

Given the lack of publicly-available data about the company (no website, no registration in NY, no officers or contact information for those officers listed in Delaware corporate records), how do you propose that KEI request this information directly from the company? Answer: The company's mailing address is publicly-available, as is a phone number. Please see, for example, <https://start.cortera.com/company/research/l6o5lxm2r/intima-bioscience-inc/>.

Also, please clarify why you are unable to release this information. Answer: Please see 37 CFR 404.14

Finally, please explain how the public can be ensured that Intima Bioscience, Inc. is an appropriate licensee, who can bring the invention to market, without even knowing who its principals are, and without the ability to contact them directly for that information.

Thank you,
Kathryn Ardizzone

On Wed, Sep 11, 2019 at 1:40 PM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Dear Ms. Ardizzone,

REL0000024997

I am unable to release this information. You may, however, request it directly from the company.

Regards,

Andy

From: kathryn ardizzone <kathrynardizzonekei@gmail.com>

Sent: Wednesday, September 11, 2019 12:59 PM

To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>

Subject: Re: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Thank you, Andy.

Can you please answer our question about Intima Bioscience's principals/list the members of its board of directors? We believe that is not too much to ask, considering that this information is not publicly-available, and Intima Bioscience apparently is not even registered to do business in the state in which it is headquartered. We need this information to effectively comment on the licenses.

Thanks,

Kathryn

On Tue, Sep 10, 2019 at 4:00 PM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Dear Ms. Ardizzone,

Answers to your questions are provided below.

Regards,

Andy

Andrew R. Burke, Ph.D.

Senior Technology Transfer Manager

National Cancer Institute

9609 Medical Center Drive, Rm 1E550

Rockville, MD 20850

Direct: (240) 276-5484

Email: andy.burke@nih.gov

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From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Monday, September 9, 2019 12:30 PM

To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>

Subject: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Dr. Burke:

Please answer the following questions related to Federal Register notice 84 FR 45503 regarding, "Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy."

1. At what stage of development are the inventions listed? Answer: Preclinical
 - a. If there has been a clinical trial, please list any NCT clinical trial numbers.
2. If the government has provided funding:
 - a. How much has been spent by the government on these trials? Answer: The technologies are preclinical.
 - b. Please identify any NIH grant numbers.
 - c. Please confirm whether grants 5R21CA216652-02 and 1R21CA216652-01A1 are associated. Answer: Please direct this question to the University of Minnesota or consult NIH Reporter.

3. Please confirm or deny whether the license will “extend to the expiration of the last to expire of the Licensed Patent Rights” as provided in the NIH Model Exclusive Patent License Agreement. Answer: This has not yet been determined.
 - a. If you deny #4, please state the duration of exclusivity.
4. Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559)?
5. According to the Federal Register notice, Intima Bioscience is “headquartered in New York.” According to the PCT applications PCT/US2016/044856, PCT/US2016/044858 and PCT/US2017/058615, Intima Bioscience has an address at 3 Columbus Circle New York, New York 10019. However, a search for the entity name “Intima Bioscience” using the NYS Department of State Division of Corporations database does not return any company with that name. A search for the entity name “Intima Capital” using the NYS Department of State Division of Corporations database does return a registered company with addresses in 3 Columbus Circle New York, New York 10019. Please confirm whether the prospective licensee is “Intima Bioscience” or “Intima Capital.” Answer: The applicant is Intima Bioscience, Inc.
6. Is the prospective licensee in this case the same company listed in the Federal Register notice 80 FR 59790, titled “Prospective Grant of Exclusive License: Development of Non-viral Adoptive Cell Transfer-based Immunotherapies (ACT) for the Treatment and Prophylaxis of Patients With Metastatic Cancer”? Answer: Yes, the applicant is the same.
 - a. Was the exclusive license described in 80 FR 59790 executed? Answer: No
 - b. If so, what is the rationale for granted additional exclusive rights to Intima Bioscience in a field of use that also relates to cancer?
7. How did the NIH determine that Intima Bioscience is an appropriate licensee? Who are the principals of the company? Answer: The preliminary determination was based on a review of the commercial development plan and supporting information submitted by the company in their application for license.
8. Does Intima Bioscience has a website? If so, please provide a link to their website. Answer: I am not aware of a website for Intima Bioscience, Inc.
 - a. Note that “Intima Capital,” a company located in 3 Columbus Circle New York, New York and registered to do business there, does seem to have a website: <http://intimacapital.com/>
 - b. Note also that a study performed by University of Minnesota Scientists Branden Moriarity and RS Ivor (co-inventors on the patent listed) in “Gene Engineering for Cancer Therapy” was funded by Intima Capital LLC.
 - c. If Intima Capital and Intima Bioscience are related, what is the relationship? Answer: Please direct this question to the company.
9. Please confirm whether the following CRADA is associated with the licensed technology:
 - a. CRADA No. C-058-2015/0, *Development and Evaluation of Intima Bioscience Proprietary Non-Viral Vectors for the Integration of Genes Encoding Mutation Specific T Cell Receptors that Have Been Identified Using NCI Proprietary Methods for the Identification of Lymphocytes and Receptors Specific for Mutated Cancer Antigens Expressed by the Autologous Cancer* Answer: The patents and patent applications listed in 84 FR 45503 are not Subject Inventions of this or any NCI CRADA.
 - b. If your answer to No. 6 is “No,” please identify any CRADAs associated with any of the subject inventions.
10. Did the NIH previously post this technology in the Federal Register under “Government Inventions available for licensing” or on the NIH’s OTT Website’s “Licensing Opportunities”? Answer: No
 - a. If “Yes,” please provide a citation for the listing(s).

11. According to the Federal Register notice Intima Bioscience, Inc. is a co-owner of the listed patent documents. Why is the NIH proposing to license rights in patents/patent applications that are already co-owned by the prospective licensee? Why is the rationale for this? Answer: Because NIH wishes to grant an exclusive license to improve the chances that the technologies will be made available to the public.
12. How has NIH ensured that the grant and scope of exclusivity are no greater than reasonably necessary to incentivize Intima Bioscience to commercialize the licensed technology? Answer: As 37 CFR 404.7(a)(1)(ii) makes clear, consideration of any written objection(s) timely received in response to the notice provided in 84 FR 45503 is a necessary component of the determination required by 37 CFR 404.7(a)(1)(ii)(C). Since the 15-day notice period for this proposed license remains open, the final determination that 37 CFR 404.7(a)(1)(ii)(C) is satisfied has not been made.

Thank you in advance for your assistance in this matter.

Sincerely,

Kathryn Ardizzone and Luis Gil Abinader

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

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Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

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Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 9/11/2019 5:13:24 PM
To: Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Hi Mark and Richard,

See KEI's further request below.

b5

Thanks,

Andy

From: kathryn ardizzone <kathrynardizzonekei@gmail.com>
Sent: Wednesday, September 11, 2019 12:59 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>
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Thanks,

Kathryn

On Tue, Sep 10, 2019 at 4:00 PM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Dear Ms. Ardizzone,

Answers to your questions are provided below.

Regards,

Andy

REL0000025009

Andrew R. Burke, Ph.D.

Senior Technology Transfer Manager

National Cancer Institute

9609 Medical Center Drive, Rm 1E550

Rockville, MD 20850

Direct: (240) 276-5484

Email: andy.burke@nih.gov

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From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Monday, September 9, 2019 12:30 PM

To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>

Subject: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Dr. Burke:

Please answer the following questions related to Federal Register notice 84 FR 45503 regarding, "Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy."

1. At what stage of development are the inventions listed? Answer: Preclinical
 - a. If there has been a clinical trial, please list any NCT clinical trial numbers.
2. If the government has provided funding:
 - a. How much has been spent by the government on these trials? Answer: The technologies are preclinical.
 - b. Please identify any NIH grant numbers.
 - c. Please confirm whether grants 5R21CA216652-02 and 1R21CA216652-01A1 are associated. Answer: Please direct this question to the University of Minnesota or consult NIH Reporter.

3. Please confirm or deny whether the license will “extend to the expiration of the last to expire of the Licensed Patent Rights” as provided in the NIH Model Exclusive Patent License Agreement. Answer: This has not yet been determined.
 - a. If you deny #4, please state the duration of exclusivity.
4. Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559)?
5. According to the Federal Register notice, Intima Bioscience is “headquartered in New York.” According to the PCT applications PCT/US2016/044856, PCT/US2016/044858 and PCT/US2017/058615, Intima Bioscience has an address at 3 Columbus Circle New York, New York 10019. However, a search for the entity name “Intima Bioscience” using the NYS Department of State Division of Corporations database does not return any company with that name. A search for the entity name “Intima Capital” using the NYS Department of State Division of Corporations database does return a registered company with addresses in 3 Columbus Circle New York, New York 10019. Please confirm whether the prospective licensee is “Intima Bioscience” or “Intima Capital.” Answer: The applicant is Intima Bioscience, Inc.
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 - b. Note also that a study performed by University of Minnesota Scientists Branden Moriarity and RS Ivor (co-inventors on the patent listed) in “Gene Engineering for Cancer Therapy” was funded by Intima Capital LLC.
 - c. If Intima Capital and Intima Bioscience are related, what is the relationship? Answer: Please direct this question to the company.
9. Please confirm whether the following CRADA is associated with the licensed technology:
 - a. CRADA No. C-058-2015/0, *Development and Evaluation of Intima Bioscience Proprietary Non-Viral Vectors for the Integration of Genes Encoding Mutation Specific T Cell Receptors that Have Been Identified Using NCI Proprietary Methods for the Identification of Lymphocytes and Receptors Specific for Mutated Cancer Antigens Expressed by the Autologous Cancer* Answer: The patents and patent applications listed in 84 FR 45503 are not Subject Inventions of this or any NCI CRADA.
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12. How has NIH ensured that the grant and scope of exclusivity are no greater than reasonably necessary to incentivize Intima Bioscience to commercialize the licensed technology? Answer: As 37 CFR 404.7(a)(1)(ii) makes clear, consideration of any written objection(s) timely received in response to the notice provided in 84 FR 45503 is a necessary component of the determination required by 37

CFR 404.7(a)(1)(ii)(C). Since the 15-day notice period for this proposed license remains open, the final determination that 37 CFR 404.7(a)(1)(ii)(C) is satisfied has not been made.

Thank you in advance for your assistance in this matter.

Sincerely,

Kathryn Ardizzone and Luis Gil Abinader

--

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 9/10/2019 7:59:40 PM
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Subject: FW: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Hi Mark,

Below is my response to KEI.

Thanks,

Andy

From: Burke, Andy (NIH/NCI) [E]
Sent: Tuesday, September 10, 2019 3:59 PM
To: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>
Subject: RE: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Ms. Ardizzone,

Answers to your questions are provided below.

Regards,

Andy

Andrew R. Burke, Ph.D.

Senior Technology Transfer Manager
National Cancer Institute
9609 Medical Center Drive, Rm 1E550
Rockville, MD 20850

Direct: (240) 276-5484
Email: andy.burke@nih.gov

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From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Monday, September 9, 2019 12:30 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>
Subject: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

REL0000025025

Dear Dr. Burke:

Please answer the following questions related to Federal Register notice 84 FR 45503 regarding, "Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy."

1. At what stage of development are the inventions listed? Answer: Preclinical
 - a. If there has been a clinical trial, please list any NCT clinical trial numbers.
1. If the government has provided funding:
 - a. How much has been spent by the government on these trials? Answer: The technologies are preclinical.
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 - c. Please confirm whether grants 5R21CA216652-02 and 1R21CA216652-01A1 are associated. Answer: Please direct this question to the University of Minnesota or consult NIH Reporter.
1. Please confirm or deny whether the license will "extend to the expiration of the last to expire of the Licensed Patent Rights" as provided in the NIH Model Exclusive Patent License Agreement Answer: This has not yet been determined.
 - a. If you deny #4, please state the duration of exclusivity.
1. Has the NIH sought advice from the Attorney General (as is required under 40 USC § 559)?
2. According to the Federal Register notice, Intima Bioscience is "headquartered in New York." According to the PCT applications PCT/US2016/044856, PCT/US2016/044858 and PCT/US2017/058615, Intima Bioscience has an address at 3 Columbus Circle New York, New York 10019. However, a search for the entity name "Intima Bioscience" using the NYS Department of State Division of Corporations database does not return any company with that name. A search for the entity name "Intima Capital" using the NYS Department of State Division of Corporations database does return a registered company with addresses in 3 Columbus Circle New York, New York 10019. Please confirm whether the prospective licensee is "Intima Bioscience" or "Intima Capital." Answer: The applicant is Intima Bioscience, Inc.
3. Is the prospective licensee in this case the same company listed in the Federal Register notice 80 FR 59790, titled "Prospective Grant of Exclusive License: Development of Non-viral Adoptive Cell Transfer-based Immunotherapies (ACT) for the Treatment and Prophylaxis of Patients With Metastatic Cancer"? Answer: Yes, the applicant is the same.
 - a. Was the exclusive license described in 80 FR 59790 executed? Answer: No
 - b. If so, what is the rationale for granted additional exclusive rights to Intima Bioscience in a field of use that also relates to cancer?
1. How did the NIH determine that Intima Bioscience is an appropriate licensee? Who are the principals of the company? Answer: The preliminary determination was based on a review of the commercial development plan and supporting information submitted by the company in their application for license.
2. Does Intima Bioscience has a website? If so, please provide a link to their website. Answer: I am not aware of a website for Intima Bioscience, Inc.
 - a. Note that "Intima Capital," a company located in 3 Columbus Circle New York, New York and registered to do business there, does seem to have a website: <http://intimacapital.com/>
 - b. Note also that a study performed by University of Minnesota Scientists Branden Moriarity and RS Ivor (co-inventors on the patent listed) in "Gene Engineering for Cancer Therapy" was funded by Intima Capital LLC.
 - c. If Intima Capital and Intima Bioscience are related, what is the relationship? Answer: Please direct this question to the company.
1. Please confirm whether the following CRADA is associated with the licensed technology:
 - a. CRADA No. C-058-2015/0, *Development and Evaluation of Intima Bioscience Proprietary Non-Viral Vectors for the Integration of Genes Encoding Mutation Specific T Cell Receptors that Have Been Identified Using NCI Proprietary Methods for the Identification of Lymphocytes and Receptors Specific for Mutated Cancer Antigens Expressed by the Autologous Cancer* Answer: The patents and patent applications listed in 84 FR 45503 are not Subject Inventions of this or any NCI CRADA.

- b. If your answer to No. 6 is "No," please identify any CRADAs associated with any of the subject inventions.
1. Did the NIH previously post this technology in the Federal Register under "Government Inventions available for licensing" or on the NIH's OTT Website's "Licensing Opportunities"? Answer: No
 - a. If "Yes," please provide a citation for the listing(s).
 1. According to the Federal Register notice Intima Bioscience, Inc. is a co-owner of the listed patent documents. Why is the NIH proposing to license rights in patents/patent applications that are already co-owned by the prospective licensee? Why is the rationale for this? Answer: Because NIH wishes to grant an exclusive license to improve the chances that the technologies will be made available to the public.
 2. How has NIH ensured that the grant and scope of exclusivity are no greater than reasonably necessary to incentivize Intima Bioscience to commercialize the licensed technology? Answer: As 37 CFR 404.7(a)(1)(ii) makes clear, consideration of any written objection(s) timely received in response to the notice provided in 84 FR 45503 is a necessary component of the determination required by 37 CFR 404.7(a)(1)(ii)(C). Since the 15-day notice period for this proposed license remains open, the final determination that 37 CFR 404.7(a)(1)(ii)(C) is satisfied has not been made.

Thank you in advance for your assistance in this matter.

Sincerely,

Kathryn Ardizzone and Luis Gil Abinader

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 11/15/2019 6:44:16 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]
Subject: RE: Response to KEI re A-506-2019
Attachments: Response to KEI C Cassedy Comments_Final.docx

Hi Mark,

Here's the final draft of the letter. I plan to send it out before COB today.

Thank you,

Andy

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Thursday, November 14, 2019 6:22 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: RE: Response to KEI re A-506-2019

Looks good to me. I would suggest

b5

b5

From: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Sent: Thursday, November 14, 2019 11:48 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: RE: Response to KEI re A-506-2019

Hi Mark,

I've added an additional paragraph along the lines you requested. Please take a look and let me know if you have any concerns.

Thanks,

Andy

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Wednesday, November 6, 2019 11:26 AM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: FW: Response to KEI re A-506-2019

REL0000025052

Andy,

b5

b5

Thanks

From: "Burke, Andy (NIH/NCI) [E]" <andy.burke@nih.gov>
Date: November 6, 2019 at 9:59:13 AM EST
To: "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>
Subject: RE: Response to KEI re A-506-2019

Hi Mark,

This is addressed at length in the final determination.

b5

b5

Andy

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Wednesday, November 6, 2019 9:55 AM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Subject: RE: Response to KEI re A-506-2019

Thanks Andy. Given their comments about exclusivity, I think the response should include

b5

b5

From: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Sent: Wednesday, November 6, 2019 9:42 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: RE: Response to KEI re A-506-2019

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Tuesday, November 5, 2019 5:41 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Subject: RE: Response to KEI re A-506-2019

Can you send me their comments? Thx

From: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Sent: Tuesday, November 5, 2019 3:17 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: Response to KEI re A-506-2019

Hi Mark,

Richard signed the final determination for the above-referenced exclusive license application today, so I've prepared a response to KEI's objection (attached). Please let me know if you have any question or concerns.

Thank you,

REL0000025052

Andy

Andrew R. Burke, Ph.D.

Senior Technology Transfer Manager

National Cancer Institute

9609 Medical Center Drive, Rm 1E550

Rockville, MD 20850

Direct: (240) 276-5484

Email: andy.burke@nih.gov

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health/ NCI
9609 Medical Center Drive, Suite 530
Rockville, MD 20852
Office (240) 276-5530
Facsimile (240) 276-5504

November 15, 2019

Claire Cassedy
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009
+1.202.332.2670
claire.cassedy@keionline.org

Subject: Comments Submitted in Response to Federal Register Notice 2019-21519 (84 FR 52890), entitled
"Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies
for Cancer"

Dear Ms. Cassedy:

Thank you for providing us with your comments regarding the above-referenced notice ("Notice"). As you indicated, your comments were submitted on behalf of several organizations and we kindly request that you share our response with these same parties.

Prior to posting the Notice, the NCI determined that the prospective licensee was qualified, both technically and financially, to be granted an exclusive license to the Government's intellectual property in the specified fields of use. 37 C.F.R. § 404.7(a)(1)(i) provides an opportunity for public comment and possible objection to the proposed license.

NCI considered all written objections timely received in response to the Notice and has since determined that the requirements specified in 37 C.F.R. § 404.7(a)(1)(ii)(A-C), and 37 C.F.R. § 404.7(a)(1)(iii) have been satisfied.

The technologies described in the Notice will be applied in the development of certain cell therapies for the treatment of cancer. Considering, for example, the magnitude of investment required to develop such products and the overall probability of success, a degree of exclusivity is an appropriate incentive to the commercial partner. Moreover, any exclusive license executed pursuant to the Notice would be limited to the narrow fields of use specified in the same. The purposeful limitations contained in these fields of use will allow for additional companies utilizing distinct technical approaches to further license the Government's rights. This approach helps to create robust competition in the therapeutic space occupied by these technologies and increases the likelihood that a cancer treatment embodying the inventions secures regulatory approval and becomes available to the public.

Sincerely,

Andrew Burke, Ph.D.
Senior Technology Transfer Manager

REL0000025052.0001

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 11/14/2019 4:48:27 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]
Subject: RE: Response to KEI re A-506-2019
Attachments: Response to KEI C Cassidy Comments_draft 11-14-19.docx

Hi Mark,

I've added an additional paragraph along the lines you requested. Please take a look and let me know if you have any concerns.

Thanks,

Andy

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Wednesday, November 6, 2019 11:26 AM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: FW: Response to KEI re A-506-2019

Andy,

b5

b5

Thanks

From: "Burke, Andy (NIH/NCI) [E]" <andy.burke@nih.gov>
Date: November 6, 2019 at 9:59:13 AM EST
To: "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>
Subject: RE: Response to KEI re A-506-2019

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b5

b5

Andy

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Sent: Wednesday, November 6, 2019 9:55 AM
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Sent: Tuesday, November 5, 2019 5:41 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Subject: RE: Response to KEI re A-506-2019

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Sent: Tuesday, November 5, 2019 3:17 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: Response to KEI re A-506-2019

Hi Mark,

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Thank you,

Andy

Andrew R. Burke, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute
9609 Medical Center Drive, Rm 1E550
Rockville, MD 20850

Direct: (240) 276-5484
Email: andy.burke@nih.gov

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health/ NCI
9609 Medical Center Drive, Suite 530
Rockville, MD 20852
Office (240) 276-5530
Facsimile (240) 276-5504

b5

Sincerely,

Andrew Burke, Ph.D.
Senior Technology Transfer Manager

From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 9/27/2019 2:30:08 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

b5

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

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From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Friday, September 27, 2019 10:10 AM
To: Berkley, Dale (NIH/OD) [E] <berkeleyd@od.nih.gov>
Subject: RE: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

b5

From: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Sent: Friday, September 27, 2019 10:06 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: RE: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

Hi Mark,

Here's my proposed response to KEI's further email.

Thanks,

Andy

Dear Ms. Ardizzone,

b5

Regards,

REL0000025097

Andy

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Friday, September 27, 2019 9:39 AM

To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Cc: James Love <james.love@keionline.org>

Subject: Re: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

Dear Dr. Burke,

Thank you for your email. I have referred to your September 10 email where the question is addressed. It states:

Question: Please confirm or deny whether the license will "extend to the expiration of the last to expire of the Licensed Patent Rights" as provided in the NIH Model Exclusive Patent License Agreement.

Answer: This has not yet been determined.

Since September 10, 17 days have passed, and the NCI has rejected KEI's comments and determined that the license is appropriate. As you are aware, under Section 209 of the Bayh Dole Act, this requires that NCI has determined that the scope (including term) of the license is not greater than reasonably necessary. So, presumably something should have changed since your September 10 email.

I will pose the question to you again: Has the NCI established the duration of the prospective license to Intima Bioscience? Answer: No, for the reason described above.

A "yes" or "no" answer would be responsive, and it would be appreciated.

If your answer is "yes," what is the term?

If your answer is "no," when do you anticipate making such a determination? Answer: Currently unknown, since the timeline of negotiation is determined as much by the responsiveness of the counterparty as it is by the NCI.

Thank you in advance for your assistance with these questions.

Kathryn Ardizzone

On Fri, Sep 27, 2019 at 9:24 AM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Dear Ms. Ardizzone,

Please refer to my email of September 10 where this questions is addressed.

Regards,

Andy

REL0000025097

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Thursday, September 26, 2019 4:42 PM

To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Subject: Re: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

Dear Dr. Burke,

Thank you for forwarding the NCI's final determination regarding KEI's comments on the license to Intima Bioscience.

Is the period of exclusivity for the subject license life of patent? Please let us know, as this pertains to a possible basis on which we may appeal the determination.

Sincerely,
Kathryn Ardizzone

On Thu, Sep 26, 2019 at 4:31 PM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Dear Ms. Ardizzone,

Please find attached a response to your comments regarding the referenced Federal Register notice.

Sincerely,

Andy

Andrew R. Burke, Ph.D.

Senior Technology Transfer Manager

National Cancer Institute

9609 Medical Center Drive, Rm 1E550

REL0000025097

Rockville, MD 20850

Direct: (240) 276-5484

Email: andy.burke@nih.gov

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From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Friday, September 13, 2019 5:23 PM

To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Cc: James Love <james.love@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; manon.ress@cancerunion.org; Peter Maybarduk <pmaybarduk@citizen.org>; Steve Knievel <sknievel@citizen.org>; ruth.lopert@gmail.com; lovesplumbing@comcast.net; Alex Lawson <alawson@socialsecurityworks.org>

Subject: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

Dear Dr. Burke:

Attached, please find the comments of Knowledge Ecology International (KEI), Union for Affordable Cancer Treatment (UACT), Public Citizen (PC), Social Security Works (SSW), LWC Health, Ruth Lopert, Manon Ress, and Terry Love regarding "Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy," 84 FR 45503, and the associated attachments.

Thank you in advance for processing and considering these comments.

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

REL0000025097

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 11/6/2019 3:16:35 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Response to KEI re A-506-2019

b5

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

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From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Wednesday, November 06, 2019 10:02 AM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: Fwd: Response to KEI re A-506-2019

Do you agree?

Sent from my iPhone

Begin forwarded message:

From: "Burke, Andy (NIH/NCI) [E]" <andy.burke@nih.gov>
Date: November 6, 2019 at 9:59:13 AM EST
To: "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>
Subject: RE: Response to KEI re A-506-2019

Hi Mark,

This is addressed at length in the final determination.

b5

b5

b5

Andy

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Sent: Wednesday, November 6, 2019 9:55 AM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
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b5

b5

From: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Sent: Wednesday, November 6, 2019 9:42 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: RE: Response to KEI re A-506-2019

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Tuesday, November 5, 2019 5:41 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
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Andrew R. Burke, Ph.D.
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From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 9/27/2019 1:24:32 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

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To: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Subject: RE: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

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On Thu, Sep 26, 2019 at 4:31 PM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Dear Ms. Ardizzone,

Please find attached a response to your comments regarding the referenced Federal Register notice.

Sincerely,

REL0000025103

Andy

Andrew R. Burke, Ph.D.

Senior Technology Transfer Manager

National Cancer Institute

9609 Medical Center Drive, Rm 1E550

Rockville, MD 20850

Direct: (240) 276-5484

Email: andy.burke@nih.gov

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From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Friday, September 13, 2019 5:23 PM

To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Cc: James Love <james.love@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; manon.ress@cancerunion.org; Peter Maybarduk <pmaybarduk@citizen.org>; Steve Knievel <sknievel@citizen.org>; ruth.lopert@gmail.com; lovesplumbing@comcast.net; Alex Lawson <alawson@socialsecurityworks.org>

Subject: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

Dear Dr. Burke:

Attached, please find the comments of Knowledge Ecology International (KEI), Union for Affordable Cancer Treatment (UACT), Public Citizen (PC), Social Security Works (SSW), LWC Health, Ruth Lopert, Manon Ress, and Terry Love regarding "Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy," 84 FR 45503, and the associated attachments.

Thank you in advance for processing and considering these comments.

REL0000025103

Sincerely,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

--

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 9/26/2019 8:30:19 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503
Attachments: Response to KEI_9-26-19.pdf

From: Burke, Andy (NIH/NCI) [E]
Sent: Thursday, September 26, 2019 4:30 PM
To: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Subject: RE: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

Dear Ms. Ardizzone,

Please find attached a response to your comments regarding the referenced Federal Register notice.

Sincerely,

Andy

Andrew R. Burke, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute
9609 Medical Center Drive, Rm 1E550
Rockville, MD 20850

Direct: (240) 276-5484
Email: andy.burke@nih.gov

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From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Friday, September 13, 2019 5:23 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: James Love <james.love@keionline.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>; manon.ress@cancerunion.org; Peter Maybarduk <pmaybarduk@citizen.org>; Steve Knievel <sknievel@citizen.org>; ruth.lopert@gmail.com; lovesplumbing@comcast.net; Alex Lawson <alawson@socialsecurityworks.org>
Subject: Comments, Prospective Grant of an Exclusive Patent License: "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc., 84 FR 45503

Dear Dr. Burke:

Attached, please find the comments of Knowledge Ecology International (KEI), Union for Affordable Cancer Treatment (UACT), Public Citizen (PC), Social Security Works (SSW), LWC Health, Ruth Lopert, Manon Ress,

and Terry Love regarding "Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy," 84 FR 45503, and the associated attachments.

Thank you in advance for processing and considering these comments.

Sincerely,

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health/ NCI
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Rockville, MD 20852
Office (240) 276-5530
Facsimile (240) 276-5504

September 26, 2019

Kathryn Ardizzone, Esq.
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009
+1.202.332.2670
kathryn.ardizzone@keionline.org

Subject: Comments Submitted in Response to Federal Register Notice 2019-18648 (84 FR 45503), entitled
"Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer
Therapy"

Dear Ms. Ardizzone:

Thank you for providing us with your comments regarding the above-referenced notice ("Notice"). As you indicated your comments were submitted on behalf of several organizations and individuals, we kindly request that you share our response with these same parties.

Prior to posting the Notice, the NCI determined that the prospective licensee was qualified, both technically and financially, to be granted an exclusive license to the Government's intellectual property in the specified fields of use. 37 C.F.R. § 404.7(a)(1)(i) provides an opportunity for public comment and possible objection to the proposed license.

NCI considered all written objections timely received in response to the Notice and has since determined that the requirements specified in 37 C.F.R. § 404.7(a)(1)(ii)(A-C) and 37 C.F.R. § 404.7(a)(1)(iii) have been satisfied.

Sincerely,

A handwritten signature in black ink, reading "Andrew Burke", is positioned above the typed name.

Andrew Burke, Ph.D.
Senior Technology Transfer Manager

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 11/5/2019 8:16:44 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: Response to KEI re A-506-2019
Attachments: Response to KEI C Cassidy Comments_draft 11-5-19.docx

Hi Mark,

Richard signed the final determination for the above-referenced exclusive license application today, so I've prepared a response to KEI's objection (attached). Please let me know if you have any question or concerns.

Thank you,

Andy

Andrew R. Burke, Ph.D.

Senior Technology Transfer Manager
National Cancer Institute
9609 Medical Center Drive, Rm 1E550
Rockville, MD 20850

Direct: (240) 276-5484

Email: andy.burke@nih.gov

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health/ NCI
9609 Medical Center Drive, Suite 530
Rockville, MD 20852
Office (240) 276-5530
Facsimile (240) 276-5504

b5

Sincerely,

Andrew Burke, Ph.D.
Senior Technology Transfer Manager

From: Knabb, Jim (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=535517D229E04963A2B928742CB80DA0-KNABBJR]
Sent: 1/16/2020 9:05:24 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Questions about Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies

OK thanks Mark.

Jim

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Thursday, January 16, 2020 3:44 PM
To: Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>
Subject: RE: Questions about Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies

You could respond that

b5

b5

b5

From: Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>
Sent: Thursday, January 16, 2020 3:33 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: FW: Questions about Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies

Hi Mark,

I received quite a few questions for the FRN here: <https://www.federalregister.gov/documents/2020/01/03/2019-28356/prospective-grant-of-an-exclusive-patent-license-development-and-commercialization-of-cd19cd22>

I addressed some of these questions previously in their comments related to the license to Lyell
(<https://www.federalregister.gov/documents/2019/08/20/2019-17866/prospective-grant-of-an-exclusive-patent-license-development-and-commercialization-of-cd19cd22>)

b5

b5

Thanks,
Jim

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Thursday, January 16, 2020 12:04 PM
To: Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>
Subject: Questions about Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies

Dear Dr. Knabb:

At your earliest convenience, please answer the following questions related to the "Prospective Grant of an

REL0000025124

Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies."

1. What is the development stage of the inventions?
2. Have there been any positive results from any of the following three clinical trials investigating the inventions not reported clinicaltrials.gov? How many patients has it been tested on so far? If you do not have this information for the Stanford trials, please provide it for the trial being conducted at the NIH Clinical Center.
3. Has CJ Healthcare agreed to substantially manufacture any product embodying the inventions in the United States?
4. Will the license terms promote access to the product in developing countries? If so, how?
5. What is the proposed duration of the license?
6. On what basis did the NIH conclude that an exclusive patent license is a necessary incentive?
7. How will the NIH limit the scope of the license to not broader than the necessary incentive?
8. Has CJ Healthcare committed to developing the product for pediatric indications?
9. Will the license require CJ Healthcare to develop the product for use in children?
10. Please list the firms that have applied for the license.
11. Has the NIH sought the antitrust advice of the U.S. Attorney General concerning the license?

Thank you in advance for your assistance.

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From: Baxter, Merissa (NIH/NCI) [F] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=792B65733B4C468089E6D1563F8A9E34-BAXTERML]
Sent: 5/14/2020 9:42:17 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)
Attachments: RE: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Thank you for the edits. Attached, please find a copy of the email I sent to KEI.

Merissa

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Thursday, May 14, 2020 3:40 PM
To: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>
Subject: RE: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

See some suggested edits. Please send me a copy of the final email after you send it.

From: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>
Sent: Thursday, May 14, 2020 2:53 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: FW: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Hi Mark,

I'm following up regarding my drafted response to KEI. Are there any changes you'd recommend, or do you think it is sufficient to send? Thanks for your input.

Best,
Merissa

From: Baxter, Merissa (NIH/NCI) [F]
Sent: Tuesday, May 12, 2020 3:40 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: McGuinness, Charlotte (NIH/NCI) [E] <m McGuinncc@mail.nih.gov>; Guyton, Nicole (NIH/NCI) [E] <darackn@mail.nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: RE: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Hello Mark,

Please find my proposed draft response to KEI attached. My supervisors (copied) have already reviewed it. Thank you for your input.

Best,

REL0000025173

Merissa

Merissa Baxter, Ph.D.

Technology Transfer Manager
Technology Transfer Center
National Cancer Institute
National Institutes of Health

9609 Medical Center Drive
Rm 1E-406, MSC 9702
Rockville, MD 20850-9702
240-276-7234 | merissa.baxter@nih.gov

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Monday, May 11, 2020 10:56 AM
To: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Cc: McGuinness, Charlotte (NIH/NCI) [E] <mcguinncc@mail.nih.gov>; Guyton, Nicole (NIH/NCI) [E] <darackn@mail.nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Subject: RE: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Merissa:

Your colleagues should have examples of responses. Here is a recent one:

b5

b5

Please

have your supervisors and me review the proposed draft.

Thanks,
Mark

From: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>
Sent: Monday, May 11, 2020 10:13 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Cc: McGuinness, Charlotte (NIH/NCI) [E] <mcguinncc@mail.nih.gov>; Guyton, Nicole (NIH/NCI) [E] <darackn@mail.nih.gov>; Chang, Kevin (NIH/NCI) [E] <changke@mail.nih.gov>
Subject: FW: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Hi Mark and Richard,

I received this email from KEI at COB on Friday. I am forwarding it along to ask how best to proceed. I have not responded to KEI. Thank you.

Best Regards,
Merissa

REL0000025173

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Friday, May 8, 2020 4:59 PM

To: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>

Cc: James Love <james.love@keionline.org>

Subject: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Dear Dr. Baxter:

Attached, please find the comments of Knowledge Ecology International regarding the "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743).

Thank you,

Kathryn Ardizzone, Esq.

Counsel

Knowledge Ecology International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

From: Baxter, Merissa (NIH/NCI) [F] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=792B65733B4C468089E6D1563F8A9E34-BAXTERML]
Sent: 5/14/2020 9:39:07 PM
To: kathryn ardizzone [kathryn.ardizzone@keionline.org]
CC: James Love [james.love@keionline.org]
Subject: RE: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)
Attachments: Response to KEI_5.14.2020.pdf

Dear Kathryn,

Attached, please find the response to Knowledge Ecology International's comments regarding the "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743).

Best Regards,
Merissa

Merissa Baxter, Ph.D.
Technology Transfer Manager
Technology Transfer Center
National Cancer Institute
National Institutes of Health

9609 Medical Center Drive
Rm 1E-406, MSC 9702
Rockville, MD 20850-9702
240-276-7234 | merissa.baxter@nih.gov

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Friday, May 8, 2020 4:59 PM
To: Baxter, Merissa (NIH/NCI) [F] <merissa.baxter@nih.gov>
Cc: James Love <james.love@keionline.org>
Subject: Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743)

Dear Dr. Baxter:

Attached, please find the comments of Knowledge Ecology International regarding the "Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases" (85 FR 22743).

Thank you,

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670



DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health/ NCI
9609 Medical Center Drive, Suite 530
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Facsimile (240) 276-5504

May 12, 2020

Kathryn Ardizzone, Esq.
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009
+1.202.332.2670
kathryn.ardizzone@keionline.org

Subject: KEI Comments “Prospective Grant of an Exclusive Patent License: Thio Compounds and Thalidomide Analogues for the Treatment of Neurological Diseases” (85 FR 22743)

Dear Ms. Ardizzone,

Thank you for providing us with your comments regarding the above-referenced notice (“Notice”).

The NCI and NIA have determined that the prospective licensee, AevisBio, Inc., is qualified, both technically and financially, to be granted an exclusive license to the Government’s intellectual property in the specified field of use.

NCI and NIA considered all written objections and comments timely received in response to the Notice and has since determined that the requirements specified in 37 C.F.R. § 404.7(a)(1)(ii)(A-C) and 37 C.F.R. § 404.7(a)(1)(iii) have been satisfied. As we have previously noted, many of the questions and issues posed in your comments and email communications have been answered multiple times previously or have nothing to do with the requirements set forth in the regulations.

Sincerely,

Merissa Baxter, Ph.D.
Technology Transfer Manager

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 11/6/2019 2:41:45 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Response to KEI re A-506-2019
Attachments: KEI_UACT_Comments_NIH_Exclusive_License_Ziopharm_18Oct2019.pdf

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Sent: Tuesday, November 5, 2019 5:41 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Subject: RE: Response to KEI re A-506-2019

Can you send me their comments? Thx

From: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Sent: Tuesday, November 5, 2019 3:17 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: Response to KEI re A-506-2019

Hi Mark,

Richard signed the final determination for the above-referenced exclusive license application today, so I've prepared a response to KEI's objection (attached). Please let me know if you have any question or concerns.

Thank you,

Andy

Andrew R. Burke, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute
9609 Medical Center Drive, Rm 1E550
Rockville, MD 20850

Direct: (240) 276-5484
Email: andy.burke@nih.gov

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REL0000025223



1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
www.keionline.org

October 18, 2019

Andrew Burke, Ph.D.
Senior Technology Transfer Manager
NCI Technology Transfer Center
9609 Medical Center Drive, RM 1E530, MSC 9702
Bethesda, MD 20892-9702
Via Email: andy.burke@nih.gov

Re: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer, 84 FR 52890

Dear Dr. Burke:

Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT) are writing to object to the "Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer," to Ziopharm Oncology, Inc. ("Ziopharm"), as described in the Federal Register notice located at 84 FR 52890.

The license would grant Ziopharm exclusive, worldwide rights in two T-cell therapies that target common cancer mutations, adding to a platform technology that Ziopharm is developing. The first cell therapy is primarily directed at mutations in the Kirsten rat sarcoma viral oncogene homolog (KRAS) gene, while the second targets mutations in the p53 tumor protein. KRAS is expressed in a variety of cancers, including pancreatic, lung, endometrial, and ovarian cancer. Mutations in p53 are expressed in cancers such as cholangiocarcinoma, melanoma, colon cancer, rectal cancer, ovarian cancer, endometrial cancer, non-small cell lung cancer, glioblastoma, uterine cervical cancer, head and neck cancer, breast cancer, pancreatic cancer, and bladder cancer. Considering the broad range of potential applications and indications, the NIH's decision about this license carries great weight for cancer patients.

We have the following objections to the proposed exclusive license to Ziopharm:

1. Our correspondence with the National Institutes of Health (NIH) concerning the prospective license indicates that the NIH has not faithfully applied the criteria in 35 U.S.C. § 209 and 37 C.F.R. § 404.7;

2. The NIH has not been completely transparent about the license, impeding the public's right to comment under 35 U.S.C. § 209(e); and
3. The NIH apparently has not sought the antitrust advice of the U.S. Attorney General regarding the license, as required by 40 U.S.C. § 559.

We note that Drew Deniger, a former NIH scientist who discovered at least one of the subject inventions, joined Ziopharm in July 2019.¹ We appreciate the fact that an inventor can play an important role in bringing an invention to practical application, by bringing passion, vision and expertise to the endeavor. That said, when an NIH employee who discovers an invention in his or her capacity as an NIH researcher is soon after employed by the company to which the NIH licenses the invention, it is particularly important for the NIH to demonstrate that it properly evaluated the criteria for granting exclusive patent licenses, located at 35 U.S.C. § 209, which includes a responsibility to protect the public's interests in the inventions it financed.

In the event that the NIH grants the license over our objections, we request that the license agreement incorporates provisions designed to safeguard the public interest and effectuate the policy objectives of the Bayh-Dole Act, as well as the governing principles of the Public Health Service (PHS) Technology Transfer Policy Manual.

Background

The prospective license concerns T-cell therapies developed by the NCI:

- E-029-2019, "HLA Class-II Restricted T Cell Receptors Against RAS with G12R Mutation" ("Invention A"); and
- E-135-2019, "T Cell Receptors Recognizing R175H or Y220 C Mutation in P53" ("Invention B").

The license would add to Ziopharm's "Sleeping Beauty platform," a suite of intellectual property rights in T-cell receptors targeting certain KRAS and p53 mutations that Ziopharm acquired from NIH pursuant to an exclusive license agreement executed on May 28, 2019.² Ziopharm believes

¹

<https://ir.ziopharm.com/news-releases/news-release-details/ziopharm-oncology-names-ncis-dr-drew-deniger-direct-tcr-t-cell>

²

<https://ir.ziopharm.com/news-releases/news-release-details/ziopharm-oncology-announces-exclusive-license-national-cancer>. Dr. Andrew Burke, the point of contact for the license, confirmed in an email to KEI dated October 17, 2019, that the prospective exclusive patent license referenced in the Federal Register at 84 FR 2537 was executed on May 28, 2019.

that the Sleeping Beauty platform “will be foundational technology to successfully targeting and treating metastatic solid tumors.”³

The table below, constructed by the NCI’s Office of Technology Transfer, demonstrates how the prospective license would complete the transfer of rights in NCI’s “Collection of mutated KRAS TCRs” to Ziopharm.

Table 1: Collection of mutated KRAS TCRs.

No.	TCR (ID in Reference)	KRAS Variant	HLA Restriction	Epitope (variant underlined)	TCR Origin	Reference
1	TCR (TRAV12N-3*01/TRBV4*01)	G12D	A*11:01	VVVGADGVGK, 10-mer	Murine	E-028-2015
2	TCR (TRAV19*01/TRBV13-1*02)	G12V	A*11:01	VVVGAYGVGK, 10-mer	Murine	E-180-2015
3	TCR (TRAV3-3*01/TRBV4*01)	G12V	A*11:01	VVVGAYGVGK, 9-mer	Murine	E-180-2015
4	TCR (TRAV4*01/TRBV5-6*01)	G12D	C*08:02	GADGVGKSA, 9-mer	Human	E-265-2015
5	TCR-1 (TRAV4*01/TRBV5-6*01)	G12D	C*08:02	GADGVGKSA, 9-mer	Human	E-175-2016
6	TCR-2 (TRAV4*01/TRBV5-6*01)	G12D	C*08:02	GADGVGKSA, 9-mer	Human	E-175-2016
7	TCR-3 (TRAV4*01/TRBV5-6*01)	G12D	C*08:02	GADGVGKSA, 9-mer	Human	E-175-2016
8	TCR-4 (TRAV12-2*01/TRBV10-2*01)	G12D	C*08:02	GADGVGKSAL, 10-mer	Human	E-175-2016
9	TCR (TRAV13-1/TRBV20-1)	G12V	DRB1*07:01	EYKLVVVGAYGVGKS, 15-mer	Human	E-181-2017
10	TCR (TRAV24/TRBV12-4)	G12C	DRB1*11:01		Human	E-181-2017
11	TRC (TRAV14/DV4*02/TRBV5-1*01)	G12V	A11:01	VVVGAYGVGK	Human	E-239-2017
12	TCR (TRAV12-3*03/TRBV1*01)	G12V	HLA-A3	VVVGAYGVGK, 10-mer	Human	E-166-2018
13	TCR (TRAV29/TRBV19*02)	G12R	DRB5*01		Human	E-029-2019
14	TCR (TRAV12*-2*01/TRBV20-1*01)	G12R	HLA-DQA1*05:05:HLA-DQB1*03:01		Human	E-029-2019

Source: <https://techtransfer.cancer.gov/availabletechnologies/e-175-2016>.

The first 12 KRAS TCRs listed in Table 1 were licensed to Ziopharm as part of the May 28, 2019 Exclusive Licensing Agreement.⁴ The last two are assigned the NIH Reference No. E-029-2019, which is covered by the instant license.

Neither of the patent applications concerning Inventions A and B has been published, limiting our ability to evaluate the technology.

We note, however, that NCI scientist Drew Deniger, who joined Ziopharm in July 2019,⁵ is one of the inventors of Invention B.⁶ He is also one of the inventors of several of the technologies

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<https://ir.ziopharm.com/news-releases/news-release-details/ziopharm-oncology-names-ncis-dr-drew-deniger-direct-tcr-t-cell>

⁴ In February 2019, the NIH announced that it was proposing licensing Inventions No. E-028-2015, E-265-2015, E-175-2016, E-181-2017, E-239-2017, and E-166-2018. See 84 Fed. Reg. 2537, <https://www.federalregister.gov/documents/2019/02/07/2019-01431/prospective-grant-of-an-exclusive-patent-license-development-and-commercialization-of-cell-therapies>. In email correspondence with KEI, Dr. Burke confirmed that the license referenced at 84 Fed. Reg. 2537 was executed on May 28, 2019.

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<https://ir.ziopharm.com/news-releases/news-release-details/ziopharm-oncology-names-ncis-dr-drew-deniger-direct-tcr-t-cell>

⁶ <https://www.ott.nih.gov/technology/e-135-2019>

covered by the May 28, 2019 Exclusive License Agreement, which was executed fewer than two months before Dr. Deniger joined Ziopharm.

A Ziopharm press release describes Dr. Deninger's role in developing the company's Sleeping Beauty platform as follows:

Since 2013, Dr. Deniger has worked at the NCI under Dr. Steven Rosenberg where he has served as Lead Investigator for the group's efforts in three initiatives: Identifying "hotspot" neoantigens for T-cell therapy; targeting neoantigens in metastatic endometrial and ovarian cancers; and non-viral gene therapy using the Sleeping Beauty platform to generate TCR-modified T cells targeting neoantigens.

"At the foundation of our TCR-T program is the partnership we have developed with Dr. Rosenberg and his team at the NCI. As an integral part of that group, Dr. Deniger has helped harness our Sleeping Beauty technology to express neoantigen-specific T-cell receptors and prepare for the start of the upcoming clinical trial in patients with solid tumors," said Laurence Cooper, M.D., Ph.D., Chief Executive Officer of Ziopharm. "As a recognized leader in the identification of neoantigens in hotspots, advancing innovative immunotherapy approaches into the clinic, and with years of expertise with the Sleeping Beauty system, we're delighted to welcome Drew to Ziopharm."

Author of multiple peer-reviewed manuscripts describing detection of neoantigen-reactive T cells for personalized cancer immunotherapy and T-cell responses to hotspot mutations, Dr. Deniger has also written validating publications related to the non-viral Sleeping Beauty transposon-transposase system. Dr. Deniger is the named inventor on patents related to TCRs recognizing mutated p53 and methods of isolating T cells having antigenic specificity for a p53 cancer specific-mutation, and has been the recipient of numerous awards in cancer immunotherapy.⁷

Ziopharm Oncology, Inc., the Prospective Licensee

Ziopharm was registered in Delaware on May 16, 2005 and in Massachusetts on December 19, 2006.

According to its most recent SEC 10-K form, Ziopharm is "a biopharmaceutical company focused on discovering, acquiring, developing and commercializing next generation immunotherapy platforms that leverage cell- and gene-based therapies to treat patients with cancer."⁸ Ziopharm states in its 10-K that the company is developing "two immuno-oncology platform technologies that utilize the patient's immune system by employing novel, controlled gene expression and innovative cell engineering technologies to designed deliver safe,

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<https://ir.ziopharm.com/news-releases/news-release-details/ziopharm-oncology-names-ncis-dr-drew-deniger-direct-tcr-t-cell>

⁸ <https://www.sec.gov/Archives/edgar/data/1107421/000119312519063978/d678734d10k.htm>

effective, and scalable cell- and viral-based therapies for the treatment of multiple cancer types.”

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According to its March 5, 2019 SEC 10-K form, Ziopharm “ha[d] not demonstrated an ability to perform the functions necessary for the successful commercialization of any product candidates.”¹⁰ The company’s operations “have been limited to organizing and staffing [the] company, acquiring, developing and securing [their] proprietary product candidates, and undertaking preclinical and clinical trials of [their] product candidates.”¹¹ The report states further that Ziopharm “do[es] not have internal research capabilities,” and that the company is “dependent upon pharmaceutical and biotechnology companies and academic and other researchers to sell or license [to them] their product candidates and technology.”¹²

In 2017, Ziopharm announced that it signed a Cooperative Research and Development Agreement (CRADA) with NCI to develop adoptive cell transfer, or ACT-based immunotherapies genetically modified using the Sleeping Beauty transposon/transposase system to express TCRs for the treatment of solid tumors.¹³

Ziopharm has executed several exclusive licenses over related inventions, including with the University of Texas MD Anderson Cancer Center over patents directed to certain non-viral Sleeping Beauty system and CAR+ T cell and bioprocessing technology; as well as the May 28, 2019 license with the NIH referenced above, over patents directed to T-cell receptors targeting certain KRAS and p53 mutations.¹⁴

Argument

1. The NIH has not demonstrated that it properly evaluated the necessity of granting an exclusive license or that it has ensured that the scope of rights will not be broader than reasonably necessary to induce the investment needed to commercialize the subject technology.

Before it may execute the proposed license, NIH must find both that granting the license is a reasonable and necessary incentive to induce a company to commercialize the technology, and

⁹ <https://www.sec.gov/Archives/edgar/data/1107421/000119312519063978/d678734d10k.htm>

¹⁰ <https://www.sec.gov/Archives/edgar/data/1107421/000119312519063978/d678734d10k.htm>

¹¹ <https://www.sec.gov/Archives/edgar/data/1107421/000119312519063978/d678734d10k.htm>

¹² <https://www.sec.gov/Archives/edgar/data/1107421/000119312519063978/d678734d10k.htm>

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<https://ir.ziopharm.com/news-releases/news-release-details/ziopharm-and-intrexon-announce-cooperative-research-and>

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<https://ir.ziopharm.com/news-releases/news-release-details/ziopharm-oncology-announces-exclusive-license-national-cancer>

“that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]” 35 U.S.C. § 209(a)(1)-(2).

We are concerned that the NIH has not conducted the analysis required by 35 U.S.C. § 209 to evaluate the necessity of granting exclusivity and determine the proper scope of the license. We address the NIH’s analysis of the necessity of exclusivity and the scope of the license below.

Necessity of Exclusivity

We are concerned that NIH has not given any meaningful consideration to the first criteria for granting an exclusive license under Section 209: that “granting the license is a reasonable and necessary incentive to-- (A) call forth the investment capital and expenditures needed to bring the invention to practical application; or (B) otherwise promote the invention’s utilization by the public[.]” 35 U.S.C. § 209(a)(1).

It is our understanding that the NIH has not undertaken a serious evaluation of the adequacy of existing incentives and subsidies, relating to practical application of the inventions, in order to evaluate whether or not exclusivity is a “reasonable and necessary incentive.”

KEI asked Dr. Andrew Burke, the point of contact for the license, how the NIH determined that exclusivity is a reasonable and necessary incentive, including what analysis, if any, the NIH has undertaken in reaching that conclusion. Dr. Burke responded as follows: “An identified public health need, license applicant’s commercial development ability at the time of application, 35 U.S.C. 209 and 37 CFR part 404.” He did not answer KEI’s questions about an economic analysis and consideration of other incentives.

The exchange is copied and pasted below.

KEI’s Correspondence with Dr. Burke’s Response regarding Exclusivity

3. On what basis did the NIH conclude that an exclusive license to Ziopharm was a necessary incentive under 35 U.S.C. § 209(a)(1)? **Answer: An identified public health need, license applicant’s commercial development ability at the time of application, 35 U.S.C. 209 and 37 CFR part 404.**

a. Did you perform any analysis of other incentives such as Orphan Drug exclusivity, pediatric rare disease priority review vouchers, test data exclusivity, etc? **[No Answer]**

b. Did you estimate the cost of bringing the technologies to market? **[No Answer]**

Dr. Burke’s response does not follow federal law and regulations governing exclusive licenses in federally-owned inventions. Neither 35 U.S.C. § 209 nor 37 C.F.R. § 404.7 refers to “[a]n identified public health need” or a “license applicant’s commercial development ability at the time of application.” Rather, they call upon the relevant agency to determine whether exclusivity is “a reasonable and necessary incentive to call forth the investment capital and expenditures

needed to bring the invention to practical application or otherwise promote the invention's utilization by the public[.]”

We interpret the word “necessary” in accordance with its plain meaning. Merriam-Webster defines “necessary” as “absolutely needed” or “required[.]” which is a different analysis from whether there is a public health need and the prospective licensee has the capacity to fulfill that need. A prospective licensee’s capacity to commercialize a federally-owned invention certainly is relevant to whether it should be awarded a license. But Section 209 requires consideration of more than the licensee’s capacity: it goes to whether there would be a willingness to undertake the investment in bringing a federally-owned invention to market, absent an exclusive license.

In order to conclude that an exclusive license is a necessary incentive, some analysis must be undertaken, including, for example, consideration of the other types of incentives provided by law, such as test data protection, Orphan Drug exclusivity, etc., and the likely case that the developer can bring other patented inventions into the project, for which exclusivity exists. Dr. Burke’s statements to KEI indicate that the NIH has not undertaken such an analysis.

Even if NIH’s construction of Section 209(a)(1) were correct, we question how NIH concluded that Ziopharm is financially qualified to commercialize the subject technology. Ziopharm’s own statements call into question its capacity to bring the licensed inventions to market.

In its most recent SEC 10-Q filing, Ziopharm states as follows:

We have not generated significant revenue and have incurred significant net losses in each year since our inception. For the six months ended June 30, 2019, we had a net loss of \$28.1 million, and, as of June 30, 2019, we have incurred approximately \$594.4 million of accumulated deficit since our inception in 2003. We expect to continue to incur significant operating expenditures and net losses.¹⁵

The PHS Technology Transfer Policy Manual states that “no license applicant shall be awarded a license if that applicant [] has a current PHS license for use of a PHS invention and is delinquent in the payment of any royalties or fees due the PHS or is not meeting any commercial development milestone under the license agreement[.]”¹⁶

KEI asked Dr. Burke whether Ziopharm is “delinquent in the payment of any royalties or fees due on any patent license with NCI” and whether it “[h]as failed to meet any commercial development milestones[.]” Dr. Burke declined to answer, stating that “[t]his information is confidential.”

¹⁵ <https://ir.ziopharm.com/sec-filings/sec-filing/10-q/0001193125-19-216056>

¹⁶ <https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/300-policy.pdf>

Scope of the License

Even if NIH properly evaluated the necessity of exclusivity, before it may grant the proposed license to Ziopharm, the NIH must engage in an additional analysis: It must establish “that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]” 35 U.S.C. § 209(a)(2).

The NIH may adjust the scope of an exclusive patent license along the following parameters:

- Term of exclusivity - how long the licensee may claim a monopoly on the right to market and sell the invention (i.e., five years, ten years, life of patent, etc.);
- Territorial reach (worldwide or limited to the U.S. or a particular geographic region); and
- Field of use (i.e., targeted diseases).

Under Section 209, the scope of the license must be balanced against the incentive necessary to induce a company to commercialize a federally-owned invention. There are at least six factors that should be considered when evaluating the necessary incentive:

1. The costs of financing research and development and bringing the invention to market, including obtaining FDA approval;
2. The government’s investment in R&D and the development stage of the technology;
3. Any expected additional subsidies from governments or charities, including, for example, the Orphan Drug Tax Credit or additional grants or continued or new collaborations with the NIH or other government agencies;
4. The existence of other incentives, including, for example, test data protection, Orphan Drug exclusivity and awards of priority review vouchers;
5. The anticipated cost to manufacture the resultant invention; and
6. The expected post-market entry profitability of the invention, by year.

KEI asked Dr. Burke “[h]ow has/will NIH ensured that the licensing terms satisfy 35 U.S.C § 209(a)(2); namely, that the scope of the license is no broader than necessary.” He responded that the determination can only be made after the public comment period has closed.

With respect to the duration of the license specifically, KEI asked:

Is the period of exclusivity for the license to be life of patent or less than life of patent? If your answer is that the period of exclusivity is yet to be negotiated, have you ever considered a shorter period of exclusivity than life of patent? Will you consider one with respect to this license?

Dr. Burke responded: "The term of the license has not yet been established." He did not answer whether NIH has ever considered a shorter period of exclusivity than life of patent, or whether he would consider a shorter term than life of patent for the instant license.

Based on previous correspondence between KEI and Dr. Burke, as well as with other NIH technology transfer officers, it appears that the NIH's policy, when determining the scope of an exclusive patent license, is to consider only whether to limit the field of use, and to routinely grant the broadest possible rights in terms of duration of the license and territorial reach.

The terms of the May 28, 2019 Exclusive License Agreement, disclosed in Ziopharm's most recent SEC 10-q report, appear to confirm this. The duration of the May 28, 2019 license agreement is life of patent and the territorial reach is worldwide.¹⁷ Other NIH technology transfer officers have told KEI that NIH typically grants exclusive licenses for "life of patent."

Section 209(a)(2) requires that the analysis regarding the scope of an exclusive license is a fact-specific, case-by-case determination. If, in every instance, the NIH negotiates a license for "life-of patent" when a shorter time period would suffice, it is not complying with Section 209.

3. The NIH has not been fully transparent about the license, impeding the public's right to comment under 35 U.S.C. § 209(e).

A federal agency may not grant an exclusive license in government-owned technology without first notifying the public of the prospective license, allowing a minimum 15-day period for the public to comment, and considering all timely submitted comments. 35 U.S.C. § 209(e).

In order for the public to meaningfully participate in the notice-and-comment process, it must have basic information about the licenses.

We appreciate the fact that Dr. Burke answered some of KEI's questions. He failed, however, to answer several questions that were directed at information germane to the analysis required under Section 209. The questions Dr. Burke declined to answer were as follows:

- "Did you perform any analysis of other incentives such as Orphan Drug exclusivity, pediatric rare disease priority review vouchers, test data exclusivity, etc?"
- "Did you estimate the cost of bringing the technologies to market?"
- "If . . . the period of exclusivity is yet to be negotiated, have you ever considered a shorter period of exclusivity than life of patent? Will you consider one with respect to this license?"
- "Did you seek the antitrust advice of the U.S. Attorney General regarding the license?"
- "What are royalty rates/payments will the NCI receive for the license?" and

¹⁷ <https://www.sec.gov/Archives/edgar/data/1107421/000119312519216056/d777738d10q.htm>

- “Is Ziopharm delinquent in the payment of any royalties or fees due on any patent license with NCI? Has it failed to meet any commercial development milestones under any exclusive patent license agreement with NCI?”

With respect to all but the last two questions listed above, Dr. Burke declined to provide any answer whatsoever. With respect to the questions regarding royalty payments, Dr. Burke declined to answer on the basis that the requested information is confidential. We note that in Ziopharm’s most recent SEC 10-q filing, the company disclosed in detail the terms of its May 28, 2019 Exclusive License Agreement with NCI, including the terms of its royalty payments.

We thus object to the license on the grounds that the NIH has withheld relevant information without a valid basis for doing so, impeding the public’s right of comment under Section 209(e).

4. The NIH apparently has not sought the antitrust advice of the U.S. Attorney General regarding the license, as it is required to do under 40 U.S.C. § 559.

We object to the license unless the NIH first obtains the antitrust advice of the United States Attorney General, who confirms that the license would not be anticompetitive.

Under the Federal Property and Administrative Services Act, 40 U.S.C. §§ 101 *et seq.*, “[a]n executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law.” 40 U.S.C. § 559(b)(1).

This includes when the NIH proposes to grant an exclusive license in federally-owned technology. “Property” is defined at 40 U.S.C. § 102 to mean “any interest in property,” with certain exceptions that do not include patents. Similarly, Section 559 creates certain exceptions that do not include patents.

41 C.F.R. § 102-75.270 supports the notion that the term “property” in Section 559 includes intellectual property rights such as patents.

41 C.F.R. § 102-75.270 - Must antitrust laws be considered when disposing of property?

Yes, antitrust laws must be considered in any case in which there is contemplated a disposal to any private interest of -

(a) Real and related personal property that has an estimated fair market value of \$3 million or more; or

(b) Patents, processes, techniques, or inventions, irrespective of cost.

KEI asked Dr. Burke whether the NIH requested the advice of the U.S. Attorney General concerning the license. He did not answer. In the past, the NIH has asserted its position with respect to 40 U.S.C. § 559 as follows:

“The statute you reference is directed to the disposal (assignment) of government property. It has little relevance to our patent licensing activities, which are principally government by the Bayh-Dole Act and its regulations.”

The NIH’s interpretation of 40 U.S.C. § 559 is incorrect.

The Bayh-Dole Act expressly incorporates federal antitrust laws. 35 U.S.C. § 209(a)(4) allows a federal agency to grant an exclusive license only if the license “will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws.” 35 U.S.C. § 211 provides that “[n]othing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law[.]” The Bayh-Dole Act sets out the areas in which the statute “shall take precedence over any other Act which would require a disposition of rights in subject inventions[.]” 35 U.S.C. § 210, and mentions 21 separate statutes, but not the FPASA.

Second, the term “disposal” is not a defined term under 40 U.S.C. § 102 of the FPASA, and is not limited to “assignment” or “sale.” In fact, there are many examples of regulations and laws that include licensing amongst dispositions, either explicitly or by implication.

If NIH grants a fully-exclusive license to a federally-owned invention for life of patent, and allows termination of the license only in narrow, vaguely-defined circumstances, then it is effectively disposing of a government property interest so as to trigger 40 U.S.C. § 559.

This is a particularly important issue in this license, where a non-exclusive license to the subject T-cell therapies can and should be available to any firm developing these inventions. The NIH is creating a monopoly where a monopoly should not exist.

5. In the event that the NIH decides to grant the license over our objections, we recommend that the NIH includes a series of provisions designed to safeguard the public interest and ensure that the license implements the governing principles in the PHS Technology Transfer Manual.

In the event that the NIH proceeds with the license, KEI requests that it includes the following provisions to protect the public’s interest in NIH-owned technology:

1. **Price discrimination.** Any medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.

2. **Low and middle income countries.** The exclusive license should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide something that will give effect to the policy objective in the “United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy,” which states the following: “PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries.”
3. **Global registration and affordability.** The license should require Ziopharm to disclose the steps it will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.
4. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.
5. **Years of exclusivity.** We propose the license reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddl case. We propose that the exclusivity of the license be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the license could be reduced by one year for every \$500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.”
6. **Transparency of R&D outlays.** The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will

note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.” Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

Conclusion

We object to the proposed license for the reasons stated herein. If the NIH proceeds with the license over our objections, we urge that it incorporates the provisions listed herein that are designed to protect the public's investment in the subject technologies.

Sincerely,

Knowledge Ecology International
Union for Affordable Cancer Treatment